PB83-144204

Toxaphene: Decision Document and Federal Register Notice

(U.S.) Environmental Protection Agency
Washington, DC

Sep 82

U.S. Department of Commerce
National Technical Information Service
NTIS

PB83-144204

EPA 540/9-82-027

TOXAPHENE: Decision Document

Office of Pesticide Programs
U.S. Environmental Protection Agency
September 1982

REPRODUCED BY
NATIONAL TECHNICAL
INFORMATION SERVICE
U.S. DEPARTMENT OF COMMERCE
SPRINGFIELD, VA. 22161

EXECUTIVE SUMMARY

This Decision Document details the scientific basis which supports the Agency's final regulatory decision relating to the future registration status of toxaphene-containing pesticides. After carefully reviewing the risks and benefits associated with toxaphene use, the Agency has determined that stringent regulatory measures, including cancellation of most toxaphene registrations, are necessary to reduce adequately the environmental and human health risks resulting from the use of toxaphene.

Toxaphene-containing pesticides are registered for use on about 300 sites as an insecticide and herbicide with a wide variety of use patterns. Approximately 33 million pounds of toxaphene were applied to cropland and livestock in 1976; of that usage, 22 million pounds were applied to cotton. Since 1976, toxaphene annual usage on cotton has declined to an estimated 2.5 million pounds or less; total annual usage has declined to approximately 16 million pounds. The major uses of toxaphene are for control of cotton, beef cattle, wheat, soybeans, sorghum, and peanuts.

Because of its extensive use and environmental transport mechanisms, toxaphene use results in a significant risk of adverse ecological effects. It poses risks of chronic effects (e.g., backbone effects) to aquatic, avian and mammalian species, and in particular to fish. Exposure

50272-101

REPORT DOCUMENTATION PAGE

1. REPORT NO. EPA 540/9-82-027

2.

3. Recipient's Accession No. PB83 144204

4. Title and Subtitle

Toxaphene Decision Document and Federal Register Notice

5. Report Date

6.

7. Author(s)

USEPA, Office of Pesticide Programs

8. Performing Organization Rept. No.

9. Performing Organization Name and Address

U.S. Environmental Protection Agency
401 M Street, SW
Washington, D.C. 20460

10. Project/Task/Work Unit No.

11. Contract(C) or Grant(G) No.

(C)

(G)

12. Sponsoring Organization Name and Address

Same as 9 above

13. Type of Report & Period Covered

14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document contains detailed information regarding EPA's determination concluding the Rebuttable Presumption Against Registration (RPAR) process for toxaphene-containing pesticides.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement

19. Security Class (This Report)

20. Security Class (This Page)

21. No. of Pages 192

22. Price

(See ANSI-Z39.18)

See Instructions on Reverse

OPTIONAL FORM 272 (4-77)
(Formerly NTIS-35)
Department of Commerce

to the species of concern can result through direct application, aerial transport, or toxaphene runoff from treated fields or cattle holding areas, and from leaching or overflow from toxaphene disposal sites. In addition, the risks of acute toxicity to aquatic organisms and population reductions in non-target organisms are posed to sensitive species which may be exposed to toxaphene by numerous exposure mechanisms, including those cited above. Certain endangered fish and avian species are also subject to these chronic and acute effects because of toxaphene contamination of their habitats and food sources.

The Agency has defined the risk to humans in terms of the increased lifetime probability of cancer due to toxaphene exposure. Applicators may be exposed to toxaphene both dermally and via inhalation during application procedures. For some applicators, there appears to be a substantial increase in cancer risk. Although it is difficult to quantify toxaphene exposure and risk to the general population, it is predictable that certain populations will receive exposure as a result of toxaphene residues in food and water. Of particular concern are local populations of fish consumers in areas where significant fish contamination has been demonstrated.

The Agency has determined that the risks arising from most uses of toxaphene are greater than the social, economic, and environmental benefits of those uses. Accordingly, the

Agency has determined that immediate cancellation of toxaphene registrations for those uses is the only appropriate course of action to avoid unreasonable adverse effects upon the environment.

Toxaphene products may continue to be registered for scabies treatment of cattle and sheep in vat dips and spray-dip machines contingent on modifications in the terms and conditions of use. Toxaphene registrations also may be continued for the control of armyworms, cutworms and grasshoppers on cotton, corn, and small grain, if changes are made in the terms and conditions of their registrations which, among other things, limit use to situations where a prior finding of emergency need for toxaphene has been made in these circumstances. Continued registration of toxaphene also will be permitted for use only in the Virgin Islands and Puerto Rico to control mealybugs and pineapple gummosis moth on pineapples and weevils in bananas, subject to modifications in the terms and conditions of use.

Existing stocks of toxaphene may be used for specified time periods under very limited terms and conditions because such use is judged to be the most desirable means of achieving disposal of these stocks.

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I. INTRODUCTION

A. General Background and Organization of this Decision Document

The Federal Insecticide, Fungicide, and Rodenticide Act as amended (FIFRA), 7 U.S.C. 136 et. seq., and regulations implementing it require the Environmental Protection Agency (EPA) to review the risks and benefits of the uses of pesticides. On May 25, 1977, EPA issued a Notice of Rebuttable Presumption Against Registration and Continued Registration (RPAR) of pesticide products containing toxaphene (EPA, 1977). The rebuttable presumption was based on validated studies showing that toxaphene was oncogenic in rats and mice, resulted in other chronic or delayed toxic effects, was acutely toxic to aquatic organisms and was responsible for population reduction in nontarget organisms.

In addition to these risks, the RPAR notice listed six other possible adverse effects of toxaphene for which insufficient evidence existed at that time to initiate a rebuttable presumption. These included mutagenicity, endocrine effects, reproductive effects, enzymatic effects, population reduction in nontarget avian species, and fatality to members of an endangered species (brown pelicans). The Position Document 1 (PD-1) issued with the Notice of Rebuttable Presumption describes these studies in detail.

The Agency invited rebuttal or other comment on the risks identified in the PD 1 bearing on the presumption against toxaphene registration. The comments received and the Agency's response to them are contained in Appendix A.

The Agency also requested registrants and other interested parties to submit data on the other possible adverse effects of toxaphene and indicated that it would continue to investigate these possible adverse effects and might issue a supplementary Position Document, if warranted. The Agency did not issue a supplementary position document on toxaphene; but these six additional possible adverse effects and the comments received on them are also discussed in Appendix A.

This Decision Document addresses the risks and benefits of toxaphene, and proposes a final regulatory decision for the uses of toxaphene.*/

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*/ Toxaphene is registered for application to approximately 300 sites. In evaluating the risks and benefits of toxaphene, the Decision Document has focused primarily on the major uses of the pesticide which include cotton, beef cattle, wheat, soybeans (insecticidal and herbicidal), sorghum, and peanuts. Sufficient data and/or resources were not available to individually assess the benefits and risks for all 300 uses of toxaphene. However, because the minor use applications are sufficiently similar to application techniques for major uses, reasonable conclusions can be drawn regarding the risks of the minor uses of toxaphene. Occupational exposure/risk would be similar for minor and major uses. In addition, the adverse ecological effects attributable to toxaphene applications on minor sites should be roughly proportional to the relative volume used (i.e. toxaphene applied to minor sites versus major sites) due to toxaphene's mode of transport.

On the benefits side, available data indicate that only small volumes of toxaphene are applied to the vast majority of registered sites. In addition, alternative insecticides are registered for most toxaphene minor uses. Furthermore, substantive data have not been received by the Agency in support of continued registration for most minor uses. To the extent that volumes of usage are small and efficacious alternatives are available, the cancellation of toxaphene on minor use sites would not be expected to significantly affect the agricultural economy.

This document contains six chapters. Chapter I is this introductory section. Chapter II discusses the chemical and environmental characteristics of toxaphene. Chapter III assesses the potential ecological effects risk from the use of toxaphene. Chapter IV assesses the potential human risks. Chapter V estimates and summarizes the economic benefits of toxaphene and describes the assumptions and limitations of these estimates. Chapter VI describes the possible regulatory options and modifications to reduce the risks of toxaphene and sets forth the final decision selected by the Agency.

B. Legal Background

1. The Statute

Under FIFRA Section 3(a) (7 U.S.C. 136a (a), all pesticide products must be registered before they may be sold or distributed. Before the Administrator may register a pesticide product, however, he must determine that its use will not result in "unreasonable adverse effects on the environment," which is defined by section 2(bb) of FIFRA to mean "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." In other words, any decision about pesticide registration or continued registration must take into account both the risks and the benefits of the use of the pesticide.

Section 6(b) of FIFRA authorizes the Administrator to issue a notice of intent to cancel the registration of a pesticide or to change its classification if it appears that the pesticide or its labeling "does not comply with the provisions of [FIFRA] or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment." Thus, the Administrator may cancel the registration of a pesticide whenever he determines that it no longer satisfies the statutory standard for registration, which requires, among other things, that the pesticide not cause "unreasonable adverse effects on the environment" [FIFRA Section 3(c)(5)(C)].

2. The RPAR Process

The Agency has designed a process, known as the Rebuttable Presumption Against Registration (RPAR) process, to gather risk and benefit information about pesticides which appear to pose unreasonable risk to health or to the environment. This process, designed to allow an open, balanced decision with participation by all interested groups, is set forth in 40 CFR 162.11. These regulations describe various risk criteria, and provide that an RPAR shall arise if the Agency determines that any of the risk criteria have been met. Once a notice of rebuttable presumption has been published, registrants, applicants and other interested persons may submit evidence in rebuttal or in support of the presumption. Anyone also may submit evidence on the economic, social, and environmental benefits of any use of the pesticide. If the presumptions of risk are not rebutted, the benefits evidence submitted to or gathered by the Agency must be evaluated and considered with the risk information. The Agency also analyzes various risk reduction methods and their costs to determine if a pesticide's use may be regulated such that its risks are outweighed by its benefits. If an adequate balance between risks and benefits cannot be reached for a specific use, the registration for that use must be cancelled, or, in the case of a new application, denied.

II. CHEMICAL AND ENVIRONMENTAL CHARACTERISTICS

This Chapter identifies the basic chemical and physical properties of toxaphene, including chemical composition and analytical method, persistence in soil and water, and potential for transport through the environment. More detailed evaluations of the potential exposure of humans and wildlife to toxaphene are presented in the Agency's Risk Assessment, found in Chapters III and IV of this document.

A. Chemical Composition

Toxaphene (chemical name, chlorinated camphene) is a complex mixture of polychlorinated compounds made by chlorinating camphene to a chlorine content of 67 to 69 percent. Toxaphene contains at least 177 components (Holmstead et al., 1974) with no single component of this mixture being a principal active ingredient. Thus, the word "toxaphene" does not refer to a pesticide containing a principal active ingredient with associated impurities, but rather to a complex mixture of chemical compounds possessing various degrees of biological activity and having differing physico chemical properties.

About two-thirds of the C_{10} compounds in toxaphene are isomers which have the empirical formula $C_{10}H_{11}Cl_7$, $C_{10}H_{10}Cl_8$, and $C_{10}H_9Cl_9$. Most of the remaining compounds have similar empirical formulae, ranging from

$C_{10}H_{12}Cl_6$ to $C_{10}H_9Cl_7$. Based on analysis by mass spectroscopy (MS), it is estimated that 26 of the above components, each present in amounts of 1.0 to 2.5 percent (%), make up 40 percent of toxaphene.

Routine gas chromatographic (GC) analyses for toxaphene utilize packed columns. This method of analysis does not yield a single well-defined peak, but rather a broad envelope upon which 12 to 25 peaks are superimposed. The shape of the envelope and the relative intensities of the various peaks also change as the parent compound undergoes environmental or metabolic degradation. The breadth of the envelope renders the electron capture detector less sensitive to toxaphene compared to single peak residues. This breadth also results in overlap of the toxaphene gas chromatogram with peaks generated from other interfering pesticides and environmental chemicals, which increases the difficulties in the quantification of toxaphene residues.

The state-of-the-art method of toxaphene analysis employs capillary column GC (Ribick et al., 1982). Gel permeation chromatography separates the xenobiotics from natural organic components. This is followed by florisil chromatography which separates the contaminants into two fractions. Finally, a silica gel step separates toxaphene from PCBs, hexachlorobenzene, aldrin and heptachlor. The remaining interferences (chlordane, BHC, some DDT, DDE, and

DDD) in the toxaphene fraction are resolved on the high resolution wall-coated open tubular (WCOT) capillary column. An on-line computerized data handling system eliminates these resolved interferences and quantifies toxaphene residues by integrating the chromatographic peaks which are definitely assignable to toxaphene components and which elute without interference (generally about 30 peaks). This area is compared to the total area of all peaks in the standard (approximately 80 peaks). This careful procedure necessarily leads to a conservative (low) estimate of toxaphene. The resolved components can be confirmed as chlorinated terpenes by negative ion mass spectrometry (NIMS), which also detects any contaminants present. Highly chlorinated terpenes are not naturally-occurring compounds (Faulkner and Fenical, 1977; Baker and Murphy, 1976).

As stated above, toxaphene is a mixture of at least 177 chlorinated terpenes, and since each component will have slightly different physicochemical properties, the components will have different fates and affinities for different compartments of the environment. The result is that toxaphene residues present in air or fish samples will not show a GC pattern identical to the pattern for technical toxaphene. Consequently even though the term "toxaphene" is often used, the term should be interpreted as "toxaphene-like compounds" when used to describe residues in environmental samples - even if there were no uncertainties in sampling, extraction or instrumental detection sensitivity.

Since toxaphene is a complex mixture of compounds, technical toxaphene will be characterized by a range for all physical constants. This fact is likely responsible, in part, for the widely differing values for physical parameters reported in the literature (Cohen et al., 1982). Aqueous solubilities at ambient temperature, for example, have been reported as low as 0.037 parts per million (ppm) (Lee et al., 1968) and as high as 3 ppm (Brooks, 1974). The following physical properties of technical toxaphene are taken from a recent EPA/Oak Ridge National Laboratory report (EPA, 1979): physical form: amber, waxy solid; melting point: 65° to 90°C; vapor pressure: 0.17 to 0.4 mm Hg at 25°C; aqueous solubility: 37 micrograms/liter at ambient temperature; average molecular weight: 414; percent chlorine content: 67 to 69%.

B. Environmental Characteristics

The metabolic pathways of the 177 compounds which make up the chemical toxaphene are far from fully understood. Available evidence indicates that toxaphene is persistent in the environment, is readily transported, and is capable of accumulation at high levels in biological organisms.

1. Persistence: Soils

Under certain conditions, toxaphene has been shown to persist in soil for many years. Foster et al. (1956), studying the effects of insecticide spray accumulation in soils on crop plant growth, determined that repeated applications of toxaphene accumulated in the soils and affected growth rates of several vegetables and field crops. Nash and Woolson (1967) studied the persistence of chlorinated hydrocarbon insecticides in soils and reported that 45% of the toxaphene applied to Congaree sandy loam soil remained after 14 years. Swoboda and coworkers (1971) reported recovery of 10 to 20% of toxaphene applied to Houston black clay soil after 10 years. The percent recovery depended on the original application rate. Measurements of toxaphene persistence in a California sandy clay soil over a nine year period indicated a four year half-life for the insecticide (Hermanson et al., 1971). Nash and coworkers (1973) studied the comparative extraction of chlorinated hydrocarbon insecticides from sandy loam soils 20 years after treatment. Soils that were treated with 112 kilograms/hectacre (kg/ha) of toxaphene in 1951 and contained an average (all plots) of 55.8 ppm in 1962, still contained an average of 24.6 ppm (three extraction methods) in 1971, indicating a half-life of toxaphene in this soil of slightly over 10 years.

Others, however, have reported a much shorter half-life for toxaphene in soils. The field persistence studies of McDowell et al. (1977) on Mississippi Delta soil indicated a toxaphene half-life of only 1.6 years. Seiber et al. (1975) measured toxaphene concentrations in California cotton fields 6 to 12 months after spraying. After 6 months, 5 ppm toxaphene remained in the soil, and after 12 months the toxaphene concentration was 3.5 ppm, indicating a half-life of slightly over a year in this California soil. Other experiments of Seiber et al. (1979) on toxaphene persistence in California cotton fields report that two months after application, 50% of the applied toxaphene remained in the soil.

Although a wide range of half-life values for toxaphene in soil have been reported (a few months to 11 years), different application rates, soil types and climate conditions account for much of the variation in toxaphene persistence. As Le Fleur et al. (1974) concluded from studies of toxaphene soil-solvent interactions, toxaphene persists long beyond the growing season and hazardous accumulations in soil, water and air are a real possibility.

2. Persistence: Water

The only data on the persistence of toxaphene in water are from the few cases where toxaphene was illegally used as a pesticide to control populations of undesirable fish. Stringer and McMynn (1960) reported that, in an instance where 100 parts per billion (ppb) toxaphene was applied to Summit Lake, British Columbia, four years were required for the pesticide to dissipate sufficiently for fish survival.

Kallman et al. (1962) applied 50 ppb toxaphene to Clayton Lake, New Mexico, and recovered 1.0 ppb nine months later. Toxaphene persistence was studied in two different type Oregon lakes by Terriere et al. (1966). Eighty-eight ppb toxaphene were applied to a shallow biologically rich lake and after one year only 0.6 ppb remained. Five years after 40 ppb toxaphene were applied to a deep, biologically sparse lake, 2 ppb were detected. This lake could not be restocked with fish for six years after the toxaphene treatment. Johnson et al. (1966) studied toxaphene persistence in Wisconsin lakes. The lakes which were treated with 100 ppb toxaphene, could not safely be restocked with fish for approximately five years and one of these lakes showed a 1.0 ppb concentration after nine years. Water depth, biological activity, pH, temperature, sunlight and dissolved oxygen concentration have been identified as mediators of toxaphene persistence in lake water (Hughes and Lee, 1973; Fukano and Hooper, 1958; and Mayhew, 1959).

3. Bioaccumulation

Most organochlorine compounds are persistent and bioaccumulate; toxaphene is no exception. Sandborn et al. (1976) showed that toxaphene is highly persistent and accumulated several thousand times in their terrestrial-aquatic ecosystem. Aquatic organisms accumulated toxaphene concentrations 890 to 9600 times the toxaphene concentration of their water environment. Snails, algae and fish accumulated the highest levels of toxaphene.

In other studies, toxaphene residues in fish have accumulated to even higher concentrations: 4000 to 16,000 fold in yearling brook trout (Mayer et al., 1975); 10,000 to 20,000 fold in rainbow trout (Terriere et al., 1966); 15,000 to 20,600 in brook trout fry (Mehrle and Mayer, 1975a); 2000 to 50,000 in channel catfish and 37,000 to 69,000 in fathead minnows (Mayer et al., 1977); and 76,000 to 107,000 in fathead minnows (Mehrle and Mayer, 1975b). Lowe et al. (1971) reported the accumulation of 23 ppm toxaphene in oysters exposed to 1 ppb toxaphene for 36 weeks which indicates oysters have a biological accumulation factor value of 23,000.

Herring and Cotton (1970) measured pesticide residues of twenty Mississippi Delta lakes and reported that a lake in Mississippi had water residue levels of toxaphene of 1.92 ppb, sediment had toxaphene residue levels of 0.946 ppm, and that the bluegill and sunfish in the lake had accumulated 20 ppm toxaphene.

4. Transport via Agricultural Runoff

Toxaphene has been shown to persist in soils, and it can be transported to surface waters via agricultural runoff. Bradley et al. (1972) studied pesticide runoff from cotton plots treated with toxaphene and DDT. Although only 0.3 to 0.6 percent of the applied toxaphene washed into an adjoining pond, the concentration of toxaphene in the pond exceeded the 96-hour median tolerance limit of 3.5 ppb for bluegills. On 11 different calendar days (between July 8 and October 3, 1969), the level of toxaphene rose to 65.2 ppb. Of the toxaphene recovered in the runoff, 75% was found in the sediment.

Willis et al. (1976) measured toxaphene runoff from a Mississippi cotton field and found that 0.6 percent of the toxaphene applied was lost in runoff. This is a runoff loss of approximately 0.1 lb/acre, and losses from large tracts treated with toxaphene could result in serious problems. McDowell et al. (1981) have attributed fish kills and lack of fish productivity in Mississippi lakes to surface runoff of toxaphene and DDT.

Toxaphene from agricultural runoff has been detected in California surface waters for over 15 years (Cohen et al., 1982). Toxaphene concentrations ranging from 0.02 to 0.93 ppb have been measured in surface waters of the northern agricultural area, with concentrations as high as 71 ppb being measured in agricultural surface drains.

Simulations of toxaphene runoff from areas where cotton is grown in the Yazoo basin area using the Agricultural Runoff Model indicated a potential for toxaphene concentration in major river systems which approaches 50 ppb. (EPA/ERL 1980).

C. Atmospheric Transport

There is an additional area of concern for toxaphene contamination of the environment as a result of long-range atmospheric transport. This phenomenon has been discussed in detail in a supporting document found in Appendix B (EPA, 1982).

Apparent atmospheric transport of toxaphene-like material was first documented in 1974 when Bidleman and Olney (1974) reported toxaphene in air samples collected over the North Atlantic more than 1,000 miles from any site of use. Since then, toxaphene-like residues have been detected in the air over Bermuda (Bidleman and Olney, 1975), in fish, water, birds and seals in Swedish lakes and the Baltic and North Seas (Jasson et al., 1979), areas where toxaphene is not used. From 1976 to 1978, residues were found consistently (in 48 out of 60 samples) in rainfall collected over South Carolina (Harder, et al., 1980). The global pollution data for toxaphene have recently been detailed (Goldberg, 1981).

The concerns about toxaphene-like residues in the environment and the possibility of atmospheric transport are both illustrated by recent data from the Great Lakes (Schmitt et al., 1982), an area where toxaphene has not been used to any significant extent. Of the 71 fish samples (various species) from the Great Lakes analyzed during the 1976-1979 cycle of the Fish and Wildlife Service's National Pesticide Monitoring Program (NPMP), 54 contained toxaphene-like compounds identified by Fish and Wildlife as toxaphene. This appears to be a significant increase in frequency of detection of residues in Great Lakes fish over the 1970-1974 monitoring data (Schmitt, et al., 1981), where toxaphene-like material was detected in only 2 of 115 fish samples analyzed.[1/] For example, the most recent data from Lake Superior indicate that lake trout contain average residues of 3.8 ppm (six data points, range 1.9 to 7.3 ppm). The apparent atmospheric transport of toxaphene-like material is further supported by work done in 1980, under the direction of the Agency's Grosse Ile ORD laboratory, in which lake trout were collected from Lake Siskiwit, a landlocked lake on Isle Royale. Isle Royale, which is part of a National Park, is in Lake Superior near the Canadian border (Swain, 1982; USDI, 1982). Preliminary results indicate that toxaphene-like material was detected in a composite sample of 5 adult fish (range 2.8 to 3.2 ppm, three-way split of one composite sample).[1/] Similar residues have been detected in five other composite Lake

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[1/] It should be noted, however, that there have been advances in toxaphene analytical methodology (see above), so that the increase in frequency of detection could partly be explained by the improved detection ability.These data have not as yet undergone official EPA peer review (EPA, 1982).

Siskiwit lake trout samples collected by the Grosse Ile laboratory at levels in the 2-6 ppm range (EPA, 1982). There has been no known use of toxaphene on Isle Royale, and the only known input of water to Lake Siskiwit is from rainfall (Swain, 1978). Yet toxaphene-like residues occur in lake trout here to the same extent as in Lake Superior itself, strongly suggesting that the toxaphene contamination in Lake Siskiwit occurs via atmospheric transport. In addition, preliminary results (Swain, 1982) for seventeen bulk precipitation samples collected near the Great Lakes averaged 50 parts per trillion (ppt) (range 7-108 nanograms/liter (ng/l)) toxaphene.

It has been suggested that toxaphene-like residues in the environment can result from sources other than the use of toxaphene as a pesticide. Some persons have indicated that the chlorinated terpenes may be a byproduct of the bleaching process at pulp and paper mills. No data have been cited in support of this suggestion. In addition, the theory that toxaphene-derived residues can be dispersed throughout the environment as a result of atmospheric transport has been questioned by USDA, FDA and others. While the Agency is aware of published data supporting the atmospheric transport of toxaphene, the exact source or mechanism of transport of these residues to the Great Lakes is obviously an extremely important issue. However, this issue is not critical to the Agency's final decision. The risks to humans and the environment in the immediate areas of heavy toxaphene use coupled with the generally low benefits are sufficient to warranting cancellation of most uses.

III. ECOLOGICAL EFFECTS RISK ASSESSMENT

Since the issuance of the Toxaphene Position Document 1, the Agency has undertaken a full review of the available literature on toxaphene hazards to fish and wildlife, including all information supplied to it during the rebuttal process. The Agency has also investigated the potential levels of toxaphene exposure to susceptible fish and wildlife, and has analyzed the expected risk to fish and wildlife populations in light of this information. Reports of fish kills and other wildlife kills associated with major toxaphene uses have also been examined.

There is evidence that toxaphene is acutely and chronically toxic to a wide variety of important fish and wildlife species. For all major toxaphene uses, there appears to be a potential for some locally significant acute or chronic effects on fish and avian species. Based upon USDI analyses, the Agency concludes that pertinent information suggests that toxaphene is a contributory factor in the inability to reestablish a reproductively self-sustaining population of lake trout in the Great Lakes.

The levels and duration of toxaphene exposure, considered together with the nature and degree of the observed toxic effects, are the basis for the Agency's conclusion that continued high volume use of toxaphene can reasonably be anticipated to result in significant local and regional population reductions in non-target organisms. The Agency's analyses also indicate that fatalities to endangered species could occur from expected exposure levels in the habitats of certain endangered species. (See 40 CFR Sec. 162.11(a)(3)(ii)(C).)

Moreover, expected residues on seeds and leafy foodstuffs of avian species exceed the subacute dietary LC_{50}.[2] Field kills of birds have been observed following applications at and below the lowest recommended application rates. Residues in water resulting from drift and runoff to bodies of water (depending on proximity of water bodies and/or levels of toxaphene use) exceed one-half the acute LC_{50} for exposed aquatic species. (See 40 CFR Sec. 162.11(a)(3)(B)(2) and (3).)

This chapter is divided into discussions of toxaphene impacts on aquatic species, impacts on terrestrial species, and impacts to threatened and endangered species. Within each of these categories, the toxicity of toxaphene to selected species is discussed, along with the expected levels of exposure and the Agency's conclusions regarding risk to the selected species of wildlife.

A. Aquatic Species

The Agency's analysis of the impact of toxaphene residues on aquatic species has focused on freshwater species whose habitats include the lakes, ponds, rivers, and streams which are found in areas where toxaphene is used extensively. This is particularly relevant to cotton growing areas, where toxaphene has been widely and heavily used until recent years. In addition, the effects of the apparent contamination of the Great Lakes have been considered.[3].

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[2] LC_{50} means a concentration of a substance that is lethal to 50% of the test population.

1. Toxicity

Laboratory data on freshwater species found in the affected habitats indicate that toxaphene is acutely toxic (96-hour LC_{50}) at concentrations ranging from about 2 ppb for sensitive species to around 15 to 30 ppb for relatively non-sensitive species. Table III-1 summarizes the 96-hour LC_{50} values for freshwater species tested at nominal concentrations of toxaphene in laboratory studies. Statistically significant mortality in both sensitive and non-sensitive species have also been observed at very low concentrations when sustained over a number of days. Table III-2 summarizes the mortality data for selected species of fish at given concentrations of toxaphene for various life stages.

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[3] Although accumulation of toxaphene has been reported in estuarine species (Butler, 1973) and analyses of environmental fate of toxaphene indicate that concentrations of the compound may reach estuarine areas via runoff (EPA/ERL, 1980) or from rainfall (Harder et al., 1980), the lack of information presently available on estuarine mixing-dynamics and resulting toxaphene concentrations in those habitats renders the Agency unable to reach conclusions about levels of risk to those species.

Table III-1: Critical Water Concentrations For Toxaphene

96-Hour LC_{50} Values Concentration (ppb)	Number of Test Values (Glass Containers)	Number of Fish Species All Values	Lowest Value for Each Species	Number of Test Values (Polyethylene Containers[2/])
1.8 -5	21	10	12	-
>5 - 10	16	6	5	1
>10 - 15	9	6	4	1
>15 - 20	3	3	1	-
>20 - 30	7	4		3
>30	6	3		2
TOTAL	69	32	22	7

Species	Number of Tests)	Range (ppb) of 96-hour LC_{50} Values (glass containers)	Mean	Median	Range in (Polyethylene Containers[2/])
Bluegill Sunfish	(10)	2.4 - 18	4.65	3.2 - 3.4	15 - 42
Rainbow Trout	(6)	1.8 - 11	6.28	5.4 - 8.4	23 - 27
Largemouth Bass	(1)	2			
Brown Trout	(1)	3	9.5		
Channel Catfish	(3)	5 - 14 (1900)[1/]		5 - 14	

[1/] Anomaly

[2/] Toxaphene absorbs to polyethylene, thus effectively reducing the dissolved concentration in experiments conducted in polyethylene containers.

Table III-2: Effects and Mortality (Percent) in Selected Fish Species (with Statistically Significant Decreases Compared to Controls)

Concentration of Toxaphene in Water (ppb)	Duration of Exposure (days)	Brook Trout		Largemouth Bass	Bluegill Sunfish	Fathead Minnow		Channel Catfish		
		Fry (Treatment mortality %/ control mortality %/)	Yearly (Treatment mortality %/ control mortality %/)	Young	Young	Young	Adult	Fry (Treatment mortality %/ control mortality %/)	Young	Adult
0.039	15	(11/1)								
	30	(40/21)								
	60	(67/52)								
	90	(83/64)								
0.072	15	(14/1)								
	30	(50/21)								
	60	(69/52)								
	90	(78/64)								
99	30	(66/21)						(36/14)		
	60	(100/52)						(50/16)		
	90	(100/64)						(70/18)		
	180		(50/0)							
0.630	30	(100/21)						(43/14)		
	60	(100/52)						(73/16)		
	90	(100/64)						(82/18)		
	180		(100/0)							
1.8	1			0	0		0			
	2			0	0		0			
	4			0	0		0			
3.2	1			0	0		0			
	2			50	30		0			
	4			100	40		0			
5.6	1			50	20		10			
	2			100	90		60			
	4			100	100		60			
	15			100	100	50				
7.5	1								0	
	2								0	
	4					50			0	
18	1					50	60		10	
	2						100		50	
	4						100		80	50
	15									50
25	1								60	
	2								100	50
	4								100	

In addition to excess mortality, toxaphene causes statistically significant (p-0.05) observable effects on growth and on collagen content in backbones in exposed species. The changes in backbone composition appear to result in the "broken back syndrome" (Mayer _et_ _al_., 1975; Mayer _et_ _al_., 1977). The Agency has evaluated the data and conclusions from the major studies of chronic effects of toxaphene on brook trout, fathead minnow, and channel catfish (Rabert, unpublished). Table III-3 summarizes the major observed sublethal effects of toxaphene exposure to sensitive and non-sensitive species. Statistically significant sublethal effects have been observed after seven days of exposure in the newly hatched fry of the sensitive brook trout at concentrations below 0.1 ppb and after thirty days exposure in the relatively non-sensitive catfish fry at concentrations below 0.3 ppb.

2. Exposure and Risk Analysis

a. Introduction

In order to evaluate the expected exposure of aquatic organisms to toxaphene in the environment, the Agency has performed analyses of the residues expected in water following drift from aerial spraying and resulting from runoff to a major river system. Both sources of environmental exposure are significant under certain conditions, although the Agency believes that the major source of exposure to aquatic life in areas adjacent to toxaphene use sites is from runoff following application.

Table III-3: Statistically Significant (P<0.05) Effects on Growth (Percent Reduction) in Fish

Toxaphene Concentration in water (ppb)	Effect	Brook Trout Fry					Fathead Minnow Adult Fry (F_1)			Channel Catfish		
		Duration of Exposure in days										
		7	15	30	60	90	30	98	30	30	60	90
0.039	Length			–	8	15						
	Weight					46						
		(adult)										
	Collagen	–	–	33	30	16						
0.072	Length			–	9	9						
	Weight					27			2	–	–	–
	Collagen	40	13	49	30	16			6	–	–	–
0.299	Length			19	a	a						11
	Weight					a			4	17	11	10
	(adult weight reduced 24% after 6 mo.)								10	31	29	36
	Collagen	40	17	51	a	a						
0.630	Length			a	a	a			21			11
	Weight					a				13	8	6
	(adult weight reduced 43% after 6 mo.)									23	25	29
	Collagen	26	32	a	a	a						
												15

– = data available, but not statistically different from controls (P<0.05)

a = all fish died

In other areas, such as the Great Lakes area, it has been theorized that toxaphene-like residues may enter the aquatic environment in rainfall, apparently following aerial transport from other use sites, although alternative hypotheses have been offered.

b. Transport

Intentional or accidental direct application to water and drift from application are sources of biologically hazardous concentrations of toxaphene in water bodies in very close proximity to treated areas. However, the sources of the most widespread contamination of aquatic habitats are runoff from treated fields into major water systems, especially in the southeastern United States, and the potential aerial transport to aquatic habitats in the primary pathway of prevailing winds, especially the Great Lakes. The properties of toxaphene, and of the southeastern geographic areas in which it is widely used, make extensive runoff likely, and the literature examining the environmental fate of toxaphene has focused on runoff as the primary route of environmental contamination (Bradley et al., 1972; Nicholson, 1964). Uncontrolled disposal of solutions used in scabies treatment of livestock in the Southwest is another potential source of runoff contamination.

c. Yazoo Basin Model

In order to evaluate the potential exposure to aquatic organisms from runoff, the Agency has conducted an analysis to evaluate concentrations from runoff of toxaphene in the Yazoo River basin. This river basin includes 13,400 square miles in the northwest portion of the State of Mississippi. The streams analyzed begin with the Coldwater River headwaters just below the dams and extend through the Tallahatchie and Yazoo Rivers to the confluence with the Mississippi, including the major tributary, the Big Sunflower River. These river portions include approximately 308 river miles in the main stem and approximately 198 river miles of the Big Sunflower.

The Yazoo system was selected for study for several reasons: (1) the basin area is heavily cropped to cotton and soybeans; (2) the area has experienced high historic toxaphene use; (3) the river has physical characteristics which make it representative of other rivers in the southeastern United States; and (4) adequate data were available to permit a careful modelling effort. (EPA/ERL, 1980).

In a model which is designed to utilize available data and reasonable (i.e., not "worst case") assumptions, calculations of delivery of toxaphene to the river system were computed by the Agriculture Runoff Model (Donigian et al., 1977, 1978). For this analysis, all cotton acreage in the Delta region was assumed to be treated at 2 lbs/acre six times annually. While the treatment rate is realistic and possibly low in light of increased resistance of pests to toxaphene, the assumption of 100% of cotton acreage treated is high, especially in light of recent use patterns (See Chapter V). Six applications per season is below the number legally permitted; it has been estimated that there are up to 13 applications per year to cotton. Moreover, the model also assumed no treatment of soybean acreage or any other crops, although soybean production in the area is extensive and use of toxaphene for soybeans has been increasing (See Chapter V). In light of these factors, the results from the model may over- or underestimate toxaphene concentrations resulting from use patterns in the past year or two. However, as discussed below, the predicted concentrations (and resulting risks) are so great that even significantly lower concentrations would be unacceptable. No acceptable level of toxaphene loading to this river system has been identified, and significant sublethal effects have been observed at extremely low concentrations in the laboratory.

Based upon consideration of appropriate characteristics for toxaphene, such as interception by plants, disappearance rates from foliage and soil, and response to rainfall, as well as appropriate characteristics of the soil in the Yazoo basin, application practices for the area, and rainfall data, calculations of delivery of toxaphene to the various segments of the Yazoo River system were performed. The calculated toxaphene loading into the system was combined with measured data on relevant local river parameters, such as flow rate and sediment size and content, to produce estimates of the concentration of toxaphene in each of 20 river segments on a daily basis over a five-year period. The model which produces these estimates was developed by Battelle, Pacific Northwest Laboratories and is designated the Instream Transport Model. In order to capture some of the uncertainty associated with modelling of pesticide concentrations in this manner, the value for fine sediment concentration was varied from the 10th percentile of the available data to the 90th percentile. Fine sediment concentration is a primary determinant of dissolved concentrations of toxaphene because of sorption of toxaphene by the sediment. Consequently, the 90th percentile data reflecting high sediment concentrations provide a lower bound for toxaphene concentrations in water and the 10th percentile data provide an upper bound.

Based upon the circumstances of the study, maximum daily dissolved toxaphene concentrations in a five-year period are predicted to range from about 7 ppb for the high sediment case to about 42 ppb for the low sediment case in the river segment just below the confluence of the Big Sunflower and the Yazoo. For the mean sediment data, the estimated five-year high for the same river segment is about 14 ppb. Some other river segments are predicted to experience even higher five-year maximum toxaphene concentrations. For the segment in the headwaters of the Big Sunflower, concentrations are predicted to reach about 40 ppb three times in the five-year period at mean sediment concentrations.

Although five-year maximum concentrations give some indication of the virtual certainty of periodic acute effects, (i.e, fish kills), the percent of total time that biologically significant concentrations are expected to be reached or exceeded provides particularly useful information. Accordingly, the data on toxicity of aquatic species which indicate concentrations of dissolved toxaphene at which significant lethal and sublethal effects have been observed were employed in connection with the Instream Transport Model to calculate the number of days and percentage of time that such concentrations are reached or exceeded. Again, variability was captured by varying the value for sediment concentration. Based upon these computations, it is estimated that the LC_{50} value for young largemouth bass (extrapolated from data on the similarly sensitive brook trout) would be exceeded from 1.7 percent of the five-year period to 12.6% of that period for the two extremes of sediment concentration. If the mean sediment concentration is used the LC_{50} value for young large-mouth bass would be exceeded 4% of the time. These values are for the river segment around river mile 100 of the Big Sunflower. For mean sediment conditions, the number of days in five years that this LC_{50} curve would be exceeded varies from 38 to 71 days, depending on the river segment. For the much less sensitive channel catfish, the LC_{50} values for young catfish would be exceeded more than 35 days in five years in several river segments (mean sediment concentration) and the LC_{50} value for adult catfish would be exceeded 11 days in some river segments (mean sediment).

The model predicts concentrations of toxaphene likely to result in a significant aquatic wildlife risk. The period of time that concentrations exceed levels and durations shown to cause mortality and/or sublethal effects indicates major risk to fish in the system. For example, the dissolved toxaphene concentrations expected to result in chronic effects in the fathead minnow would be exceeded as much as 1160 days in five years (66% of the time) in the Yazoo River segment just north of the confluence with the Big Sunflower (mean sediment concentration). The concentration shown to cause catfish fry mortality after thirty consecutive days would be exceeded for a total of 391 days in five years in one segment of the Big Sunflower (mean sediment concentration). Concentrations resulting in chronic effects in the bluegill sunfish would be expected 78% of the total time in the segment below the confluence of the two main rivers (mean sediment concentration).

Because toxaphene concentrations of biological concern in river systems are likely to be episodic and variable with reaches of the rivers, a modelling effort such as that performed for the Yazoo basin provides a basis for evaluating expected exposures to aquatic populations over a time period sufficient to permit conclusions about risk. Because the Yazoo system is a reasonable representation of southeastern rivers and because the Agency's modelling effort represents reasonable estimates of expected exposures under the circumstances identified in the study, the Agency concludes that runoff from toxaphene application according to present registered use patterns poses an unacceptable risk to aquatic life in river systems like the Yazoo. This conclusion is supported by available data measuring toxaphene concentrations in fish sampled in the Yazoo basin and elsewhere during the National Pesticide Monitoring Program (Schmitt et al., 1981, in press).

For river systems west of central Texas, where direct rainfall and runoff do not consistently contribute significantly to flow during the growing season, the analysis does not support any conclusions about likely exposure from runoff. The analysis for exposures from direct application and drift are valid, however, for the western regions. Moreover, available information about field effects, including fish kills, includes a number of such episodes in the West. Consequently, the overall assessment of risk cannot exclude western areas based upon the information available to date.

d. Field Observation and Residue Data

A considerable body of field information attributes a large number of fish kills to the acute toxicity of toxaphene. In a few cases concurrent analyses of water for toxaphene have been reported and the concentrations usually exceeded 3.5 ppb (EPA, 1978; Flickinger and Belaire, unpublished). The gradual disappearance of largemouth bass from Lake Providence, Louisiana, reported by the Louisiana Wildlife and Fisheries Department in fishing surveys, has been attributed to toxaphene. Field observations tend to verify the environmental fate analyses performed by the Agency, although firm conclusions about causation are often difficult to support in specific field incidents due to the complexity of field conditions.

Some other lakes in the southeast, especially in the Louisiana/Mississippi Delta area, have been closed by public health officials to commercial fishing due to high pesticide residues. While toxaphene has not always been identified as the chemical responsible for the lake closing, frequently the toxaphene levels are sufficiently high that they also would close the lake. These high toxaphene residues may not only affect fish populations, but they also may pose a potential human health problem for consumers and may have an impact on the economics of the region. The effect of lake closings on commercial fishing is fairly easy to identify, but the loss of revenues and spin-off from sport- and subsistence-fishing are not readily quantified. Human dietary effects are discussed in Chapter IV.

Between 1970 and 1979, the National Pesticide Monitoring Program indicated that toxaphene-like residue levels in fish appear to have increased significantly in many parts of the country, particularly in the Great Lakes area (Schmitt et al, in press).4/ Residues in whole fish samples of lake trout, whitefish, and bloaters collected from the Great Lakes have increased from undetectable levels in 1970 to among the highest station levels in the country, despite the absence of general toxaphene use in the drainage basin. It has been hypothesized in Chapter II that a major toxaphene source may be from rainfall carried by prevailing winds from agricultural use sites in the South.*/ The residue levels present in the fish are generally higher than predicted from simple accumulation directly from water as found in laboratory tests on similar species. The implication is that toxaphene or toxaphene-like substances in the water has also entered the Great Lakes food chain, becoming more concentrated at each trophic level, ultimately becoming concentrated in the top predators. Presently there is no indication that tissue residues have peaked. If residue levels in fish from the Yazoo River are indicative of upper limits, residues may continue to rise.

4/ Although the apparent increase may in part be attributable to improvements in detection and analytical capabilities, the magnitude of recently measured residues is disturbing.

*/ There is some controversy surrounding the rainfall question. Some persons have indicated that it would be difficult to verify toxaphene as the source of chlorinated terpenes in rain water. Further, it is hypothesized that the chlorinated terpenes are produced by the pulp and paper industry as a by product during bleaching.

Investigations into the absence of reproductively self-sustaining lake trout populations in the Great Lakes indicate that the reproductive effects may only partially be explained by the presence of DDE and PCB's in the aquatic environment (USDI, 1981). Moreover, laboratory studies on other fish species report greater reproductive effects from lower levels of toxaphene than from the reported test levels of DDE and PCB. Analyses of lake trout tissue indicate that toxaphene-like residues are higher than other residue levels (USDI, 1981). Because of the comparatively lower bioaccumulation factor for these residues than for DDE and PCB, these results suggest higher toxaphene levels in the water than DDE and PCB levels. While no conclusions about reproductive effects may be drawn directly from this residue information, it is reasonable to assume that toxaphene-like residues may be a source of some or all of the reproductive impairment in lake trout populations in the Great Lakes.

B. Terrestrial Species

The Agency's analysis of the impact of toxaphene residues on terrestrial species has focused on avian species whose habitats include treated fields and the ecotone (transition area between two ecological communities) adjacent to the treated areas. Small mammals also inhabit these areas and may occasionally be exposed to acutely or chronically toxic concentrations of toxaphene, and laboratory tests and field observations indicate some hazard and some mortality. However, there is insufficient information available to evaluate the extent of the effects of toxaphene on small mammalian populations.

For certain avian species, however, information on acute and chronic toxicity, together with analyses of the environmental fate of toxaphene in the relevant habitats demonstrates a significant hazard to populations of those species found in areas of toxaphene use. Recorded incidences of field kills of birds tend to confirm this conclusion. Species which feed, nest, and rear their young in the croplands treated with toxaphene are most susceptible to this potential exposure. While these species are also subject to the effects of other agricultural practices such as tilling and harvesting, the use of chemical insecticides, often comes at times most hazardous in their life cycles. Although birds can avoid farm machinery, they generally cannot avoid the effects of applied chemicals. Table III-4 identifies some species at risk because of exposure to toxaphene in the fields cultivated with the major toxaphene-use crops. Quail and pheasant, for example, feed, nest, and rear broods in cotton, soybean, sorghum, and wheat fields. A number of other important avian species may also feed, nest or frequent most of the major croplands for which toxaphene is generally used.

Table III-4: Avian Wildlife Use of Select Crop Areas for Feeding (F), Nesting (N), and/or Brood-rearing (B)[1]

	Cotton	Soybeans	Sorghum	Peanuts	Wheat
Quail	FNB	FNB	FNB	FN	FNB
Pheasants	FNB	FNB	FNB		FNB
Partridges		F B	F		FNB
Grouse			F		F
Prairie Chickens	F		F B	F	FNB
Wild Turkeys	F	F	FNB	F	FNB
Doves	FN	F	F	F	FNB
Ducks		F	F	F	FN
Geese		F	F	F	FNB
Swans		F			F
Cranes	F		F	F	F B
Songbirds	FN	FNB	F	F	FN

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[1] Source:
Gusey, W.F. and Z.D. Maturgo. 1973. Wildlife utilization of croplands. Shell Oil Company, Environmental Affairs, Houston, Texas. 278p. Results are reported only for wildlife species which make moderate to high use of the crop areas.

1. Toxicity

Available laboratory data on avian species found in the affected habitats indicate that toxaphene is acutely toxic at concentrations ranging from 538 to 828 ppm. Table III-5 summarizes the concentrations of toxaphene in the diet which result in 5-day LC_{50} values for avian species for which laboratory results are available (Hill *et al*., 1975). In addition to 5-day LC_{50} values, data show that bobwhite quail after dietary exposure at 100 ppm reach 25% mortality in 10 days and after 50 ppm exposure reach 25% mortality in 15 days (Linduska and Springer, 1951). Newly hatched pheasant chicks fed 100 ppm and 300 ppm toxaphene for up to two months experienced significantly higher mortality than controls at both dose rates (Genelly and Rudd, 1956). Field investigations of bird mortality following spraying at 1 lb/acre indicate mortality and significant decrease in bird censuses in the second week following application. (McEwen *et al*., 1972).

In addition to excess mortality, toxaphene causes statistically significant sublethal effects in birds, including effects upon the reproductive process and effects upon backbone composition similar to that observed in fish. Table III-6 summarizes the major observed sublethal effects of toxaphene exposure to avian species. A statistically significant alteration in black duck eggshell composition has been observed following dietary exposure to 10 ppm toxaphene. Statistically significant reductions in the egg-laying period and in the hatchability of ring-necked

Table III-5: Dietary Toxicity of Toxaphene in 5-day Diets to Select Bird Species (1964-73)1/

Species	Age in Day	No. of Conc.	No. of Birds Per Conc.2/	LC50 (ppm)	95% C.L.3/
Bobwhite Quail	17	6	6	828	616-1102
Japanese Quail	17	6	14	686	523-1002
Ring-necked Pheasant	15	5	9	542	462-638
Mallard Duck	5	4	8	538	474-614

1/ Hill, E. F., R. G. Heath, J.W. Spann, and J. D. Williams. 1975. Lethal dietary toxicities of environmental pollutants to birds. U.s. Dep. Interior, Fish and Wildlife Service, Spec. Sci. Rep. -- Wildl. No. 191., 61 p.

2/ Conc. = Concentration

3/ C.L. = Confidence limit

Table III-6: Laboratory Observations of Sublethal Toxaphene Toxicity in Birds

Species	Dietary Dose (ppm)	Duration of Treatment (days)	Observation
Bobwhite quail[1/] (*Colinus virginianus*)	100	-	43% body weight loss
	50	-	32% body weight loss
Ring-necked pheasant[2/] (*Phasianus colchicus*)	300	-	Significant reduction ($P<0.005$) in egg-laying period and hatchability
Black duck[3/] (*Anas rubripes*)			
	10 and 50	-	Significant increases ($P<0.05$) in eggshell and collagen content
14-day-old unsexed[4/] ducklings	10 and 50	-	Significant alterations ($P<0.05$) in the composition of cervical vertebrae; decrease in collagen and increase in calcium
84-day-old females	50	-	
Females[5/]	10 and 50	-	Significantly higher ($P<0.01$) liver weight
	50	-	Significantly reduced ($P<0.05$) mean number of days of egg laying before incubation at end of second breeding season.
Males[5/]	50		Significantly higher ($P<0.005$) brain weight
Ducklings[4/]	50	5) 14)	Significantly reduced ($p<0.05$) growth rate in 1976 data when analyzed on an individual basis.
		28) 42)	Normal growth rate

1/ Linduska and Springer (1951)
2/ Genelly and Rudd (1956)
3/ Finley and Ludke (Unpublished)
4/ Mehrle, Finley, Ludke, Mayer, and Kaiser (1979)
5/ Haseltine, Finley, and Cromartie (1980)

pheasant eggs was observed following a dietary dose of 300 ppm toxaphene. These effects, because they can determine reproductive success, may have significant population effects. Changes in backbone structure, observed in black ducks after doses of 10 and 50 ppm toxaphene, may affect survival.

2. Exposure and Risk Analysis

In order to evaluate the expected exposure of avian organisms to toxaphene in the environment, the Agency has estimated expected initial residues of toxaphene on grass, leaves, weeds, seeds, and fruit following direct spraying. Table III-7 presents the results of those estimates. At the low application rate of 2 lbs/acre active ingredient, residues on short grass reach 480 ppm which is somewhat lower than the available dietary LC_{50} values. At all the higher application rates, residues on short grass are expected to exceed the 5-day LC_{50} for some avian species. The methods of estimation would tend to underestimate residues on grass because it assumes the residues are distributed evenly over all parts of the grass when in fact, residues and consumption would both concentrate on the upper portions. Further, field kills following spraying at 1.0, 1.5 and 2.0 lbs of active ingredient per acre resulted in acute toxicity to birds, also indicating that these environmental residue levels may be understated. Finally, the primary source of avian mortality from toxaphene in the field appears to be

Table III-7: Expected Initial Residues of Toxaphene (ppm) Following Direct Aerial Spraying[1]

Application Rates (lbs a.i./A)	Short Grass	Tree Leaves	Weeds and Seeds	Fruit
1.0	240	125	58	7
2.0	480	250	116	14
2.5	600	313	145	18
3.0	720	375	174	21
3.5	840	438	203	25
4.0	960	500	232	28
5.0	1200	625	290	35
6.0	1440	750	348	42
8.0	1920	1000	464	56

1/ Source: Hoerger, F. and E.E. Kenaga. 1972. Pesticide residues on plants: Correlation of representative data as a basis for estimation of their magnitude in the environment, p.9-27. In: Coulston, F. and F. Korte (ed). Environmental quality and safety. Vol. I. Global aspects of chemistry, toxicology and technology as applied to the environment. Academic Press Inc., New York, N.Y.

consumption of toxaphene-contaminated insects, such as grasshoppers and caterpillars. Estimates for residues on weeds and seeds would provide an estimate of external residues on insects, but would not account for residues taken up by the insect. In light of the strong capacity of many organisms for bioaccumulation of toxaphene (Sanborn et al., 1976), the dose to feeding birds may substantially exceed that associated with external residues.

Data establishing acute and long-term mortality as well as major sublethal effects in avian species at exposure levels expected in the environment following toxaphene application form the basis for the Agency's conclusion that toxaphene use poses an unreasonable risk to populations of avian species dependent upon toxaphene-treated fields and surrounding areas for feeding, broodrearing, or nesting.

A considerable body of field information attributes a large number of bird kills to the toxicity of toxaphene (McEwen et al., 1972; Finley, 1960; Flickinger and Belaire, unpublished; Flickinger and King, 1972; Hanson, 1952). In several of these incidences, toxaphene concentrations within the dead organisms were measured (McEwen et al., 1972; Finley, 1960; Flickinger and King, 1972; Flickinger and Belaire, unpublished). These field observations tend to verify the environmental fate analysis performed by the

Agency for bird habitats. However, the difficulties in determining whether other chemicals are involved and the lack of reliable information about the relationship between internal toxaphene concentrations in dead organisms and what levels are indicative of lethal levels prevent definitive conclusions about the cause of field kills. The timing and proximity of these deaths to toxaphene application sites are strongly circumstantial and toxaphene causation is consistent with the Agency's environmental fate analyses.

C. Endangered Species

Pursuant to 40 C.F.R. 162.11(a)(3)(ii)(C), the Agency's analyses of wildlife hazards from a pesticide include an investigation of whether the pesticide can reasonably be anticipated to result in fatality to members of endangered species. In addition, the Endangered Species Act declares the policy of Congress to be that all Federal agencies "shall seek to conserve endangered species and threatened species and shall utilize their authorities in furtherance of the purposes of the [Endangered Species Act]." (16 U.S.C. 1531).

1. Toxicity

For the same reasons that observed field mortality in wildlife following or related to toxaphene use does not readily support firm conclusions about causation, it is equally difficult to determine unequivocally the cause of fatalities in endangered species. Moreover, the very rarity of the members of the endangered species greatly reduces the likelihood that toxaphene-induced mortality would be discovered. Finally, laboratory data on the acute toxicity of any substance to endangered species is generally not available because of the unacceptability of such experimentation on these species.

Nevertheless, several conclusions about the risk of toxaphene to endangered species, especially fish and avian species, are supported by Agency analyses. The acute toxicity of toxaphene to endangered fish and birds is likely to fall within the range of doses observed to represent LC_{50} values in the more abundant species. Therefore, it can be confidently concluded that toxaphene is acutely toxic to endangered fish species at doses in the 2 ppb to 30 ppb range and acutely toxic to endangered avian species in the 538 to 828 ppm range. One acute toxicity study on the bayou darter (a threatened fish found in Mississippi) revealed a 96-hour LC_{50} of about 9-10 ppb (Lorio and De Blanc, unpublished).

In addition, toxaphene would be expected to result in long-term mortality in endangered fish species at doses less than 1 ppb and in long-term mortality to endangered birds at doses around 50 ppm. Finally, significant sublethal effects such as backbone changes and some reproductive changes would be expected in endangered fish at doses well below 1 ppb and in endangered birds at doses of 10 ppm (the lowest level tested) or less.

2. Exposure and Risk Analysis

In light of the ranges of expected toxic doses of toxaphene for endangered fish and birds and the Agency's environmental fate analyses for aquatic and avian habitats, any endangered fish and bird species found in the contaminated habitats would be expected to be threatened with mortality or other adverse effects from continued toxaphene exposure. Table III-8 identifies the endangered fish and avian species with a high likelihood of exposure to toxaphene. Since critical habitats for most of these species have not been identified by the Department of the Interior and since the very rarity of the species makes a location of particular habitats prior to application very difficult, there is no ready way to avoid toxaphene use in limited areas of endangered species habitats. Moreover, since runoff from treated fields is the primary route for contamination of local aquatic habitats and atmospheric transport is an additional important exposure route, the isolation of toxaphene exposure is impossible.

Table III-8: Endangered and Threatened Species with High Likelihood of Exposure to Toxaphene or Toxaphene-like Materials

Species	Habitat Where Found
Southern Bald Eagle	All States
American Peregrine Falcon	New Mexico
Brown Pelican	Coastal areas from North Carolina to Texas
Red-cockaded Woodpecker	Alabama, Florida, Georgia, Kentucky, Louisiana, Maine, Virginia, Tennessee, South Carolina, Oklahoma, North Carolina, Arkansas, Mississippi
Attwater's Prairie Chicken	Texas
Slackwater Darter	Alabama
Gila Topminnow	Arizona
Bayou Darter	Mississippi
Pahrump Killifish	Nevada
Alabama Cavefish	Alabama
Leopard Darter	Oklahoma, Arkansas
Comanche Spring Pupfish	Texas
Pecos Gambusia	Texas
Shortnose Sturgeon	Atlantic coastal rivers
Spring Pygmy Sunfish	Alabama
Longjaw Cisco[1/]	Lakes Erie, Huron, Michigan
Blue Pike[1/]	Lakes Erie, Ontario

[1/] May be extinct

Field experience with endangered and threatened species, although very limited, does tend to verify the conclusion that toxaphene use threatens these species. As one example, a bayou darter was collected in a suspected toxaphene fish kill in Bayou Pierre, Mississippi. Specimens from that fish kill were found to have significant concentrations of toxaphene and no evidence of endrin, which is the other pesticide whose use might have been related to the field kill (Dr. Suttkus of Tulane University, personal communication, 1980). Given the extraordinary difficulties associated with evaluating field mortalities in endangered species, these observations provide reasonable confirmation of the Agency's conclusion that continued toxaphene use threatens members of endangered species.

IV. HUMAN EFFECTS RISK ASSESSMENT

Toxaphene has been shown to be carcinogenic in laboratory animals. It would be prudent, therefore, to consider the possibility of a carcinogenic risk to humans. This Chapter presents the Agency's assessment of potential risk to human health posed by the continued use of toxaphene. A brief discussion of the laboratory studies is provided in Part A; the Agency's analysis of potential human exposure is presented in Part B; and quantitative estimates of the potential effect of toxaphene exposure on the lifetime cancer risk for various groups of exposed persons are set forth in Part C. Such estimates can only be taken as an indication of the possible relative magnitudes of risks but should not be considered as absolute levels of risk.

The lifetime cancer expectancy figures were developed on a worst case basis using conservative estimates of potential human exposure and calculating the 95% upper confidence levels on risk. It is noted that upper bounds on risk represent an abstract quantity more in the nature of an index number than an analytical indicator of empirically observable risk.

A. Carcinogenicity of Toxaphene

The Agency's overall conclusion concerning the potential carcinogenicity of toxaphene is based primarily on the results of two studies -- the National Cancer Institute

(NCI) bioassay and the study by Bionetics Research Laboratory -- which demonstrate that exposure to toxaphene results in an increased incidence of tumors in mice and rats. However, other laboratory studies support the conclusion derived from the NCI and Bionetics studies.[5/]

When the Toxaphene Rebuttable Presumption Against Registration (RPAR) was issued in May, 1977, the Agency identified the NCI bioassay as the basis for concluding that toxaphene produces an oncogenic response in laboratory animals. The Agency has evaluated the rebuttal comments submitted in response to the RPAR (see Appendix A) and information which has become available since the issuance of the RPAR, and has concluded that the presumption against toxaphene based on oncogenicity has not been rebutted.

5/ The Agency's conclusion on carcinogenicity is also supported by evidence that toxaphene induced a positive mutagenic response in Salmonella typhimurium strains TA-98 and TA-100 without metabolic activation, suggesting that toxaphene is a direct acting mutagen. There is some evidence to suggest that toxaphene may also be capable of inducing structural aberrations of human chromosomes. Although this information provides additional weight to the Agency's decision on oncogenicity, by itself it does not constitute sufficient evidence to initiate a Rebuttable Presumption Against Registration for mutagenicity (Hill, 1977).

Further support for the Agency's conclusion is found in the International Agency for Research on Cancer (IARC) evaluation which concludes that "[t]here is sufficient evidence that toxaphene is carcinogenic in mice and rats" (IARC, 1979). However, in their effort to apply the International Agency for Research on Cancer's guidelines for classification of carcinogenicity to NCI bioassays, Griesemer and Cueto place toxaphene in the category of "chemicals with very strong evidence for carcinogenicity in one species and no evidence in a second species" (Griesemer and Cueto, 1980).

1. NCI Carcinogenicity Bioassay (1979)

This study, sponsored by the Cancer Bioassay Program and performed under contract by Gulf South Research Institute (GSRI), demonstrated a statistically significant excess of liver tumors in laboratory mice of both sexes and at two dose levels and a statistically significant excess in thyroid tumors in laboratory rats. It should be noted that although this study, which was conducted from 1971 to 1973, did not follow current NCI protocols, subsequent laboratory audits indicate that the results are reliable.[6/]

[6/] In 1977, EPA and FDA conducted a cooperative laboratory inspection and comprehensive data audit of GSRI to assess the validity of the test results. Although several problems in the study were identified, the auditors concluded that the bioassay results were valid. The most serious problems concerned inaccurate pathologic evaluation and possible food contamination. However, any difficulties resulting from improper pathological examination of the test animals were rectified early in the study and the possibility of food contamination was dismissed after further analysis. The auditors were satisfied that the results of the bioassay were valid.

In a separate GAO lab audit conducted in 1978, GSRI was considered, on the whole, to perform bioassays properly. There was no evidence cited in the GAO report which would invalidate the results of the toxaphene study (CAG Report, 1979, p. 22).

a. Mouse Study

Male and female mice (strain B6C3F1) were fed a diet containing technical-grade toxaphene at one of two dosage levels (99 or 198 ppm) for 80 weeks and then observed for 10 or 11 weeks. Details of the dose schedule, number of animals used, and survival rates are provided in Table IV-I. Signs of general toxic effects were observed among the treated animals, and there was a significant dose related trend in mortality in both sexes when compared to matched controls ($p < 0.001$ in males and $p = 0.017$ in females).

In both male and female mice, significant increases were noted in the incidence of hepatocellular carcinomas and in the incidence of hepatocellular carcinomas combined with neoplastic nodules of the liver (see Table IV-2). No other anatomical site exhibited a statistically significant tumor incidence in either males or females following treatment with toxaphene.

Table IV-1. NCI Chronic Feeding Study In Mice

Sex and Test Group	Initial No. of Animals (a)	Toxaphene in Diet (b) (ppm)	Time on Study		Time-Weighted Average Dose (e) (ppm)	Survival rate >52 weeks
			Dosed (c) (weeks)	Observed (d) (weeks)		
Male						
Matched-Control	10	0		90-91		10/10 (100%)
Low-Dose	50	160 80 0	19 61	11	99	49/50 (98%)
High-Dose	50	320 160 0	19 61	10	198	46/50 (92%)
Female						
Matched-Control	10	0		90-91		9/10 (90%)
Low-Dose	50	160 80 0	19 61	11	99	46/50 (92%)
High-Dose	50	320 160 0	19 61	10	198	46/50 (92%)

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a/ All animals were 5 weeks of age when placed on study.

b/ Initial doses shown were toxic; therefore, doses were lowered at 19 weeks, as shown.

c/ All animals were started on study on the same day.

d/ When diets containing toxaphene were discontinued, dosed mice and their matched controls were fed control diets without corn oil for 7 weeks, then control diets (2 percent corn oil added) for an additional 3 to 4 weeks.

e/ Time-weighted average dose = $\frac{\sum(\text{dose in ppm x no. of weeks at that dose})}{\sum(\text{no. of weeks receiving each dose})}$

Table IV-2. Incidence of Hepatocellular Tumors In Mice - NCI Study

Treatment Group	Hepatocellular Carcinoma		Hepatocellular Carcinoma plus Neoplastic Nodules	
	Male	Female	Male	Female
Control (matched)	0/10 (0%)	0/9 (0%)	2/10 (20%)	0/9 (0%)
Control (Pooled)[a]	4/48 (8%)	0/48 (0%)	7/48 (15%)	0/48 (0%)
Low Dose - 99 ppm[b]	34/49 (69%)	5/49 (10%)	40/49 (82%)	18/49 (37%)
High Dose - 198 ppm[b]	45/46 (98%)	34/49 (69%)	45/46 (98%)	40/49 (82%)

a/ Pooled control group consists of matched controls from the bioassay of toxaphene, and similar bioassays on lindane, malathion, phosphamidon and tetrachlorvinphos.

b/ Time-weighted average dose.

b. Rat Study

Male and female Osborne-Mendel rats were fed a diet containing technical-grade toxaphene at one of two dosage levels (556 or 1,112 ppm) for 80 weeks and then observed for 28 or 30 weeks. Details of the dose schedule, number of animals used and survival rates are provided in Table IV-3. Although signs of general toxic effects were observed among the treated animals, there was no dose-related effect on mortality in any test group.

In male rats, the incidence of follicular-cell carcinomas or adenomas of the thyroid was dose-related when compared to the pooled controls. In female rats, the incidence of follicular-cell adenomas of the thyroid was dose-related using either the matched controls (P = 0.022) or the pooled controls (P = 0.0008). In high dose males, two of the nine follicular-cell tumors were carcinomas. All other follicular-cell tumors in the animals were adenomas. These results are summarized in Table IV-4. In addition, there was a statistically significant incidence (P = 0.034) of hepatocellular neoplastic nodules in males of the low dose group when compared to the pooled controls, but not with the matched controls. No other anatomical sites in either male or female rats had statistically significant incidences of tumors following treatment with toxaphene.

Table IV-3. NCI Chronic Feeding Study In Rats

Sex and Test Group	Initial No. of Animals (a)	Toxaphene in Diet (b) (ppm)	Time on Study Dosed (c) (weeks)	Time on Study Observed (d) (weeks)	Time-Weighted Average Dose (e) (ppm)	Survival rate >52 weeks
Male						
Matched-Control	10	0		108-109		10/10 (100%)
Low-Dose	50	1,280	2		556	47/50 (94%)
		640	53			
		320	25			
		0		28		
High-Dose	50	2,560	2		1,112	45/50 (90%)
		1,280	53			
		640	25			
		0		28		
Female						
Matched-Control	10	0		108-109		10/10 (100%)
Low-Dose	50	640	55		540	46/50 (92%)
		320	25			
		0		30		
High-Dose	50	1,280	55		1,080	48/50 (96%)
		640	25			
		0		30		

a/ All animals were 5 weeks of age when placed on study.

b/ Initial doses shown were toxic; therefore, doses were lowered at 19 weeks, as shown.

c/ All animals were started on study on the same day.

d/ When diets containing toxaphene were discontinued, dosed mice and their matched controls were fed control diets without corn oil for 7 weeks, then control diets (2 percent corn oil added) for an additional 3 to 4 weeks.

e/ Time-weighted average dose = $\frac{\Sigma(\text{dose in ppm x no. of weeks at that dose})}{\Sigma(\text{no. of weeks receiving each dose})}$

Table IV-4. Incidence Of Thyroid Tumors In Rats - NCI Study

Treatment Group	Follicular-cell Carcinoma or Adenoma	
	Male	Female
Control (matched)	1/7 (14%)	0/6 (0%)
Control (pooled)[a]	2/44 (5%)	1/46 (2%)
Low Dose - 556 ppm; male[b] 540 ppm; female	7/41 (17%)	1/43 (2%)
High Dose - 1112 ppm; male[b] 1080 ppm; female	9/35 (26%)	7/42 (17%)

[a] Pooled control group consists of matched controls from the bioassay of toxaphene, and similar bioassays on captan, chloramben, lindane, malathion, and picloram.

[b] Time-weighed average dose.

2. Litton-Bionetics Mouse Study (1978) - Sponsored by Boots-Hercules, Inc.

Male and female mice (strain B6C3F1) were given 0, 7, 20, or 50 ppm of toxaphene in the diet for 18 months; surviving mice were then kept on the control diet for an additional 6 months. After 24 months all surviving animals were sacrificed. Survival rates of treated and control mice were similar.

A statistically significant increased incidence of hepatocellular tumors (combined carcinomas and adenomas) was observed in treated male mice at the 50 ppm dose level when compared to the controls (see Table IV-5). Increased hepatocellular tumor incidence was not statistically significant for the treated females at any level of toxaphene treatment compared to the controls.

3. Other Laboratory Studies

Several other studies have ostensibly assessed the oncogenicity of toxaphene in laboratory animals. Because of various deficiencies, these studies are not sufficiently conclusive to support or rebut the Agency's conclusion that toxaphene is an oncogen. However, they clearly demonstrate that the liver is a target organism for toxaphene toxicity.

Table IV-5. Incidence Of Hepatocellular Tumors In Mice-Litton Bionetics Study

Dose Level (ppm)	Hepatocellular Tumor Incidence	
	Males	**Females**
0	10/53 (19%)	2/53 (4%)
7	10/54 (19%)	2/53 (4%)
20	12/53 (23%)	4/53 (8%)
50	18/51 (35%)	6/52 (12%)

a. Kettering Laboratory Studies of Rats, Dogs and Monkeys (1952)

Treon et al. (1952) investigated the toxic effects of toxaphene in rats, dogs, and monkeys.[7] Animals were treated for two years and those surviving to the termination of the study were sacrificed and examined.

Male and female rats of an unspecified strain were fed toxaphene at levels of 0, 10, 100, 1000, or 1500 ppm. No tumors were reported in any animals. However, in rats fed 1000 and 1500 ppm, significant liver enlargement and degenerative lesions of the liver characteristic of those induced by other chlorinated insecticides were observed. The lesions were manifested by swelling and homogeneity of the cytoplasm and peripheral arrangement of granules in the cytoplasm of hepatic cells in the central zones of the lobules. No significant lesions were reported in other viscera.

Male and female dogs of mixed breed were fed toxaphene at levels of 10 or 50 ppm. At 50 ppm, a slight degeneration of the liver was observed that was characterized by granularity and non-sudanophilic vacuolization of the cytoplasm of hepatic cells. No pathological changes in other viscera were reported.

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[7] Deficiencies identified in these studies include small sample sizes and inadequate strain identification.

Female monkeys of unspecified strain were fed 10 ppm of toxaphene. No relevant alterations of the viscera were observed during the post-mortem examination. Any "non-relevant" alterations which were present were not described.

b. Ortega Rat Study (1957)

Ortega et al. (1957) investigated the minimum dietary level of toxaphene required to produce pathologic changes in Sherman rats.[8] Toxaphene given in the diet for 2-9 months at levels of either 50 ppm or 200 ppm, resulted in no clinical symptoms or gross disease being observed in treated animals at necropsy. Histopathologic examination of treated rats showed evidence of centrolobular-cell hypertrophy, peripheral migration of basophilic granulations, distinctive cytoplasmic inclusion bodies, and parenchymal bleeding.

c. Litton-Bionetics Hamster Study (1979) - Sponsored by Boots-Hercules, Inc.

ARS Golden Syrian hamsters (males and females) were given either 0, 100, 300, or 1000 ppm of toxaphene in the diet for 18 months, with surviving males given additional treatment for a total of 21.5 months.[9] Moribund and surviving animals were sacrificed and necropsied. Histopathologic examinations were made of the tissues from target organs (liver and thyroid) of control and high dose animals and of the gross abnormalities from animals dosed with 100 or 300 ppm. Evidence of metahepatocytes was dose related, and was more evident in male animals than in female animals. However, there was no apparent compound related effect on hepatocellular neoplasms.

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[8] The major inadequacies in this study include 1) small sample size, 2) the period of observation did not extend over the expected lifetime, 3) only low doses were administered, and 4) the maximum tolerated dose was not determined.

4. Summary

In summary, studies in two species of laboratory animals demonstrate that exposure to toxaphene results in an increased incidence of liver and thyroid tumors. Other less conclusive studies, although neither directly supporting nor refuting the oncogenicity of toxaphene, show that the liver is a target organism for toxaphene toxicity. When considered as a whole and particularly in light of the NCI and Bionetics studies, the evidence clearly supports the Agency's conclusion that toxaphene is an oncogen in laboratory animals, and therefore may be a potential human oncogen.

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[9] These dose levels were based on a subchronic study that estimated the maximum tolerated dose based only on evidence of liver toxicity. Therefore, the actual maximum tolerated dose was probably not used in the study.

B. Human Exposure to Toxaphene

Use of toxaphene results in its distribution to air, water, soil, food sources, and non-target organisms. As a result, people and their food and water supplies may be exposed directly and/or indirectly to toxaphene. Toxaphene exposures can result from general dispersion of toxaphene residues to water, air, and dietary sources, or from deliberate applications (e.g., treated crops, occupational exposure). Fish exposure to toxaphene is a particular problem because of its inherent toxicity to fish (see Chapter III), and more importantly here, because fish bioaccumulate toxaphene following exposure in environmental media.

While sources of exposure cannot always be traced directly to a single toxaphene use, it is likely that most of such exposure is attributable to the high volume uses. In some instances, such as dietary consumption of treated crops and occupational exposures, toxaphene exposure can be linked directly to the specific uses involved. However, in other instances, human exposure may be the cumulative result of multiple past or current uses of toxaphene. Moreover, because of its environmental transport mechanisms, human exposure to toxaphene is not localized to areas of its use.

This section on potential human exposure to toxaphene is divided into three subjects: 1) exposure to the general public; 2) exposure to certain regional populations from contaminated fish; and 3) exposure to agricultural workers and other applicators. Where possible, the discussions are use-specific, and the sources of exposure discussed are primarily associated with the major uses.

1. Exposure to the General Population

The most likely sources of exposure to certain members of the general public from the use of toxaphene are primarily through consumption of treated crops, consumption of contaminated fish, and consumption of water from contaminated drinking water systems which either are untreated or inadequately treated for toxaphene contamination. This section discusses the potential for drinking water contamination, and presents qualitative and quantitative assessments of other potential dietary sources of exposure to toxaphene.

a. Toxaphene Residues in Water

Consumption of contaminated water is a potential source of human exposure to toxaphene. Where monitored, toxaphene residues have often been detected in surface water and less frequently in drinking water.[10] Because conventional drinking water treatment methods may not remove toxaphene, the surface water residues are especially important. This is particularly relevant to heavy toxaphene use areas, where drinking water monitoring data are limited. Moreover, to the extent that certain rural populations may have untreated drinking water sources, the surface water data are directly applicable.

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[10] Toxaphene has also been detected in sediment samples from Florida, the lower Mississippi River and Mississippi Delta Lakes at concentrations up to 2.46 ug/l (Matthew, 1975; Barthel, et al., 1969; Herring and Cotton, 1970).

In Alabama, the Flint Creek watershed, which drains an agricultural district where toxaphene use on small cotton farms is the major pesticide source, was monitored during the years 1959 to 1965 (Cohen, et al. 1961; Grzenda and Nicholson, 1965; Grezend, et al. 1964; Nicholson, 1969; Nicholson, et al. 1964, 1966). Toxaphene was detected in paired samples of raw Flint Creek water and treated drinking water obtained from Flint Creek at concentrations ranging from the limit of detection, with a mean of approximately 0.07 ug/l.[11/] The toxaphene concentrations in treated and untreated water samples were not significantly different, indicating that treatment of drinking water did not reduce toxaphene concentrations.

In data collected by EPA's STORET system in the Yazoo River Basin, toxaphene residues up to 3.0 ppb were detected during the period 1975-1978. A mathematical model residues in the Yazoo River system predicted of possible contamination

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[11/] In this experiment, actual residues may have averaged about 0.14 ug/l because the recovery was approximately 50%.

of those waters at values far in excess of 1 ppb for substantial periods of time if toxaphene use on cotton were at historical levels (See Chapter III). Where surface water residues have been measured in connection with fish kills in several states, residues as high as 50 ppb (50 ug/l) have been detected, with most such values exceeding 1 ppb (1 ug/l) (EPA, 1980 PIMS Report).

In California, Johnston, et al. (1967) detected toxaphene residues in surface effluents in Panoche drain water (X = 2.009 ug/l; range = 0.100 to 7.900 ug/l) and San Joaquin Valley tile drainage effluents (X = 0.528 ug/l; range = 0.130 to 0.950 ug/l). Bailey and Hannum (1967) also found toxaphene in surface water samples (X = 0.23 ug/l). The San Joaquin District, California Department of Water Resources (1963-1969) detected toxaphene in tile drainage effluents (0.02 to 0.5 ug/l), surface drains in Central Valley (0.04 to 71.00 ug/l), Central Valley surface waters (0.02 to 0.93 ug/l), and California bays and surface waters.

Toxaphene is a potential drinking water contaminant because there is limited capability to remove toxaphene from water. Use of powdered and granular activated carbon is an excellent method for removing toxaphene from water, but more conventional treatment practices do not work as well (Love, 1978; Cohen, et al., 1960, 1961(a) and (b); Robeck, et al., 1965). While there were almost 40,000 public water systems in the United States in 1978 (EPA, 1978), Lykens and Demarco (in review) estimated that less than 500 public water systems were using activated carbon in 1976.

Results from monitoring between 1969 and 1976 indicate detection of small quantities of toxaphene residues in the drinking water of certain areas, although data measurements for most samples were at or below the detection limit[12] (SRI Report, 1977). However, it is interesting to note that many of the locations with positive values were in states where there is reportedly relatively little toxaphene use.

Because data permitting sound quantitative estimates of consumption of toxaphene through drinking water are not available, the Agency's quantitative risk assessment does not include this component. However, the limited available monitoring data do provide clear evidence of toxaphene contamination of water under certain circumstances, often at episodic levels. Modelling such as that performed for the

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[12] Methods of analysis were not specified in the EPA reports of these data. Therefore, the reliability of these results is uncertain. Moreover, the data which indicate detection of small quantities of toxaphene, may either be valid data or they may be artifacts of inconsistencies in the manner in which laboratory technicians recorded data measurements, which were at or below the limits of detection. It would appear that many recorded some measurements at the limits of detection as zero, others as less than the detection limit, and others as the detection limit itself. In view of this uncertainty and the great difficulty encountered in measuring a complex mixture such as toxaphene, it is quite possible that measureable quantities of toxaphene were absent from all of the drinking water recorded in this data file.

Yazoo, although not designed to estimate contamination of end-use drinking water, also suggest that toxaphene contamination of water is predictable in certain use areas. Therefore, the potential for human exposure to toxaphene resulting from the consumption of contaminated water should not be discounted or ignored.

b. Toxaphene Residues in Food

Toxaphene is used directly on certain food crops and animals. In addition, because of drift during application and atmospheric and environmental transport, toxaphene dietary exposure may also come from sources other than residues in directly treated crops and animals. Because of uncertainty in the methodology used to measure toxaphene residues, and the limited amount of residue data for many target and all nontarget foodstuffs, it is difficult to assess potential dietary exposure to the general population. However, based on the available descriptive information, it is clear that the potential exists for toxaphene exposure to some segments of the general population.

Dietary exposure has frequently been estimated on the basis of tolerance levels[13], assuming that residues are present in individual foods to the full extent permitted by their tolerances, and that the foods are uniformly distributed throughout the country. However, toxaphene is a pesticide for which tolerances were established pursuant to the "Spray Residue Hearings" reported on in the Federal Register of March 11, 1955. Residues resulting from the use of toxaphene were determined by the method for organic chlorine, and the toxicity of toxaphene was considered to be about the same as that of DDT (Federal Register, March 11, 1955, pp. 1495). Therefore, unlike most tolerances, toxaphene tolerances may not be based on actual measured toxaphene residues or on toxicity data generated in studies using toxaphene. Accordingly, the tolerance levels are not likely to be reliable predictors of residues associated with application of the pesticide.

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[13] A tolerance is the maximum permissible residue level allowable after treatment with a pesticide. Tolerances for pesticides are set by EPA and enforced by FDA and USDA. Current permanent tolerances for toxaphene are listed in 40 CFR 180.138; interim tolerances are in 40 CFR 180.319.

In an effort to assess the actual prospects for toxaphene residues in individual foods, the Agency has reviewed the data from FDA's pesticide-food monitoring programs. Those data revealed that although residues are not frequently detected in the major use crops, positive toxaphene residues were detected in 20 of 32 peanut samples in 1978, in 8 of 61 samples in 1979 and in 1 of 44 samples in 1980. Positive residues have also been detected through monitoring efforts in dry soybeans and in wheat processed as animal feed. Using data developed as part of its Total Diet Program, FDA has estimated that the average dietary intake of toxaphene for the years 1971-1976 was 3×10^{-6} mg/kg/day.

However, this estimate may not include all dietary sources of toxaphene, or may not be sufficiently representative of all foods within a group.*/

In addition, dietary exposure to toxaphene may result from the consumption of fish and wildlife. Toxaphene or toxaphene-like residues have often been detected in fish from both areas of heavy use and areas of nonuse (see discussion in section 2 below). Residues in fish have been reported by the FDA's surveillance monitoring program; however, it is unclear how many of these residues exceeded FDA's action level of 5 ppm. Field sampling programs in Alabama soybean fields (Causey et al., 1972) and in North Carolina cotton fields (Smithson, 1978) indicate that game species collected near or in toxaphene-treated fields contain toxaphene residues in edible portions. Analysis of bobwhite quail and rabbits indicated increasing residues following multiple applications which approach or exceed 5 ppm in body tissues.

These data indicate that although it may be difficult to reliably estimate the quantity, there is a potential for dietary exposure to toxaphene from a relatively broad spectrum of contaminated foodstuff. However, it is expected that, under most circumstances, the amount of dietary exposure to toxaphene of the general population would be considerably less than the regional and occupational exposures discussed below.

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*/ The Total Diet Program consists of examination of ready-to-eat foods, collected as market basket samples from retail stores and prepared for consumption by dieticians in institutional kitchens. Twenty or thirty baskets are collected each year from different cities.

2. Regional Dietary Exposure from Fish

Contamination of fish presents a particular problem for certain regional populations, particularly in areas of heavy toxaphene use. However, to the extent that toxaphene and/or toxaphene-contaminated fish are transported outside of use areas, the exposure could be broader.

In developing this assessment, the Agency has evaluated the impact of consumption of toxaphene-contaminated fish on populations in two regions, the Mississippi Delta and the Great Lakes areas. These areas were chosen because of the generally high fish consumption of the populations, and the availability of reliable quantitative information on fish residue levels of toxaphene and/or toxaphene-like compounds and consumption patterns. (However, see Section III-16 for discussion of toxaphene-like residues in the Great Lakes.) These areas should not be considered unique. Rather, these two areas should be considered representative of similar situations which could exist elsewhere in the country. In the one instance (Mississippi Delta), the residues in fish are undoubtedly related to heavy toxaphene use in the area; in the other (Great Lakes), the residues do not appear to be attributable to local toxaphene use, but it has been theorized that is may be related to atmospheric transport of toxaphene.

Moreover, although the Agency has addressed toxaphene exposure through fish as a local problem, it could be more widespread. Because of the large commercial fishing industries in areas such as the Great Lakes, if the residues found indicate that toxaphene contamination is a problem in those areas, toxaphene-contaminated fish could be reaching the general marketplace.

a. Mississippi Delta Area

Toxaphene use in the Mississippi Delta area has traditionally been very extensive, primarily as a result of its use on cotton. Fish residue data from this area indicate widespread toxaphene contamination of fish.[14/] For various socio-economic reasons, much of the population in this area consumes large quantities of fish, and therefore is likely to have an unusually high dietary exposure to fish containing toxaphene.

1) Residue Profile

Estimates of toxaphene levels in fish from lakes and rivers in the Mississippi Delta have been derived from two independent data sources: (1) an interim report "Recognition of potential health hazard from high pesticide residues in

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[14/] Several years ago, three lakes in this area were closed to commercial fishing because of pesticide contamination. Although high DDT residues were cited, the lakes could have also been closed because of high toxaphene residues. Notwithstanding the ban on commercial fishing and posting of the lakes, these lakes continued to be some of the most heavily fished lakes in the Delta area.

fish from various lakes in Mississippi" In Annual Report No. 9, Mississippi Epidemiologic Studies Program (ESP), Mississippi State University (1977); and (2) the 1977 and 1979 surveys of the National Pesticide Monitoring Program (NPMP) for Fish reported by the Columbia National Fisheries Research Laboratory, U.S. Fish and Wildlife Service. Data from the Mississippi ESP report represent individual analyses of 24 fish of five species (bluegill, crappie, bass, catfish and carp) collected in 1975 from 11 Delta lakes in Washington, Sunflower and Bolivar counties.[15] The NPMP data are for five composites each comprising from two to five fish of a species collected from the Yazoo River at Redwood. Fish from the ESP study were deheaded, scaled and eviscerated prior to grinding for extraction, as constitutes an official sample of fish as defined by the FDA. The NPMP analyses are of ground homogenates of whole-fish composites. All residues are reported in parts per million (ppm) ground weight.

Median toxaphene levels for both data sets are virtually identical: 9.0 ppm for the 24 ESP fish and 8.9 ppm for the five NPMP composites. ESP residues ranged from "not detected" (nd) to 131 ppm; 15 of 24 (62%) exceeded 5 ppm as did fish from seven of the 11 lakes. Residues for the five NPMP composites range from 6.3 to 18.7 ppm. Toxaphene residues exceeded 5 ppm in all six species encountered in the two surveys.

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[15] Expanded fish monitoring by the Mississippi Pesticide Hazard Assessment Project (formerly the Mississippi ESP) is now underway in 11 Delta lakes and the Sunflower River. Toxaphene analyses of 30 fish composites representing six species are expected by late 1982.

2) Consumption Profile

In a 1975 survey of fish consumption patterns of families in three counties in the Delta area[16/] (Interim report cited above), it was determined that within a population of 440 people, only 25 did not eat fresh fish at all.[17/] Most of the respondents reported eating fish between one and three times a week; however, 5% reported eating fish at least five times a week.

Fish Eaten (times/week)	Frequency	%Responding
None	25	5.7
0-1	22	5.0
1-2	203	46.1
2-3	108	24.5
3-4	45	10.2
4-5	15	3.4
5 or more	22	5.0
Total	440	

Based on information relating to the source and type of fish eaten, it was also determined that approximately 48% of the fish eaters ate only locally caught fish, with much of this local catch coming from noncommercial individual fishermen. When questioned about their fishing sites, the greatest majority indicated that they fish the local lakes.

[16/] In conjunction with the survey, fish samples taken from lakes in these areas were analyzed for toxaphene residues. These results are discussed above.

[17/] The survey was limited to fresh fish, and did not include canned tuna, sardines, etc.

3) Exposure Estimate

Based on the information above, it is reasonable to conclude that a segment of the population in the Mississippi Delta area may be exposed to significant amounts of toxaphene through the consumption of contaminated fish. Because of the temperate weather in this area, it is expected that fish will be caught and consumed throughout the year.

Using the following assumptions, based in part on the consumption and residue information discussed above, the Agency developed an exposure estimate for this population.

1. The individual weighs 70 kg.
2. All fish eaten are caught locally.
3. Periodic, but frequent, toxaphene exposure is toxicologically comparable to daily toxaphene exposure.[18]
4. Fish are consumed three times a week.
5. Each fish serving is one-half pound.
6. Fish are contaminated with 9 ppm toxaphene.[19]

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[18] Toxaphene tends to accumulate and be retained in the lipid portion of tissues. Theoretically, this would "make it available, under appropriate conditions, for recirculation within the body allowing continuous or repeated exposure of target organs long after the original dose has ceased or when multiple low doses are received and accumulated to a critical level" (FDA, 1973).

[19] Median value from residue data discussed in IV.B.2.a.1).

Under the conditions described above, it is estimated that many residents of the Mississippi Delta area could receive toxaphene exposure of 1.3×10^{-2} mg/kg/day from the consumption of contaminated fish alone. People who consume either more fish (e.g., five or more times a week) or fish containing higher residues would have greater exposure. It is also reasonable to assume that many of the people in this subpopulation receive additional toxaphene exposure from other sources (e.g., occupational exposure).

b. Great Lakes Area

Unlike the Mississippi Delta area, the Agency is aware of no records indicating that toxaphene has been used in the Great Lakes area to any great extent. Nevertheless, recent monitoring data indicate that there may be potentially widespread contamination of fish in the Great Lakes by toxaphene or toxaphene-like residues. If the contamination is due to toxaphene it raises two concerns relative to the potential for human exposure: 1) Large amounts of fish are caught and presumedly eaten by sport fisherman in the area, making unusually high dietary exposure to toxaphene likely, and 2) millions of pounds of fish are caught in the Great Lakes annually by commercial fisherman, thereby making widespread dietary exposure to contaminated fish a reasonable possibility.*/

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*/ Even if the contamination is due to to toxaphene-like contaminants there still may exist a problem even though not derived from toxaphene use.

l) Residue Profile

Direct estimates of levels of apparent toxaphene-like compounds in Great Lakes fish populations have been derived from two sources: the 1977 and 1979 surveys of the National Pesticide Monitoring Program (NPMP) for Fish (Columbia National Fisheries Research Laboratory), and a limited number of composites of lake trout collected in 1980 from Lake Huron and from Lake Siskowit on Isle Royale, Lake Superior, analyzed at EPA's Large Lakes Research Station (ERL-Duluth), Grosse Ile, Michigan, (Swain 1982). The NPMP includes 13 Great Lakes sampling stations (three each on Lakes Superior and Michigan, two on Lakes Huron, Erie and Ontario, and one on Lake St. Clair). Composites of 10 individual species were analyzed (lake trout, brown trout, whitefish, bloater, walleye, yellow perch, channel catfish, rock bass, white sucker and carp).

There are currently no known toxaphene analyses of Great Lakes salmon derived by capillary column methodology or by packed-column with cleanup procedures shown to adequately resolve toxaphene components from PCB's and other contaminants. Thus possible toxaphene levels in chinook and coho salmon for Lakes Michigan, Huron and Superior have been estimated indirectly from their 1978-1980 PCB levels reported by the Michigan Department of Natural Resources (Publication Numbers 3730-0031 and 3730-0038), and, then multiplying those levels of toxpahene or toxaphene-like compounds relative to PCB ratios for lake trout calculated for each lake from the NPMP and EPA data. The Agency has assumed that PCB and toxaphene-like residues will bioaccumulate in essentially the same proportions among salmonid species inhabiting the same body of water. Further, the Agency has assumed that levels of toxaphene-like residues in Great Lakes steelhead and brown trout are similar to those in lake trout.

Levels in lake trout were highest in fish from Lake Huron followed by Lake Michigan and Lake Superior. No lake trout or salmon were collected from Lakes Erie or Ontario.

Levels among the nine remaining species sampled exhibited generally lower levels than did lake trout, and levels tended to be lower in fish from Lakes Erie and Ontario than in the other lakes. Thus to derive an "average level" of toxaphene-like residues for Great Lakes fish consumption, it was necessary to weight the salmonid and non-salmonid levels estimated for each lake, by the respective commercial and sport fishing harvests reported for each lake. Although the sport fishing harvest estimates are conservative and only approximate for each lake, they are sufficiently accurate for purposes of weighting.

Median levels of these toxaphene-like materials for lake trout composites from Lakes Superior, Michigan and Huron were 3.1 ppm (range = 1.9-7.3), 7.1 ppm (range =

5.5-8.5), and 19.0 ppm (range = 9.0-25.8), respectively. Those for the non-salmonid species ranged from 3.3 ppm for bloaters from Lake Michigan to "nd" for certain of the sucker, carp, walleye or rock bass composites from Lakes Huron, Erie or Ontario.

From 1981 U.S. commercial fish harvest data (ref.), the 1978 Michigan DNR estimates of the salmonid sport fishing harvest from Michigan waters of the Great Lakes (ref.), and an approximation of the U.S. salmonid harvest for the remainder of the Great Lakes, it is estimated that the salmon/trout sport fishing harvest equals approximately 60 million pounds: 40 million pounds from Michigan waters and an approximated 20 million pounds from the remaining waters. It is also estimated that 70% of this harvest is from Lake Michigan, 20% from Lake Huron and 10% from Lake Superior. The total U.S. commercial harvest of non-salmonid table species is reportedly 17 million pounds, and it is assumed that the respective sport fishing harvest is 8 million pounds. In total, it is estimated that a total of 60 million pounds of salmonid species and 25 million pounds of non-salmonid tables species are harvested annually from U.S. waters of the Great Lakes. The salmonid catch represents approximately 70% of the total Great Lakes harvest of table fish.

Using the percentages 70, 20 and 10, the respective harvests of salmonids from Lakes Michigan, Huron and Superior to weight the median toxaphene levels for lake trout (7.1, 19.0 and 3.1 ppm) from the respective lakes provides a weighted average of approximately 9 ppm toxaphene for the lake trout harvest. PCB levels in Chinook and coho salmon averaged .97 and .45 of those in lake trout. Assuming that residues of these toxaphene-like materials also are present and in the same ratio as in lake trout, they will be expected to average essentially 8 ppm. The average toxaphene-like level for the U.S. harvest of non-salmonid table fish (nearly 70% which occurs in Lakes Michigan, Huron and Superior) is estimated at 2 ppm.

Weighting the 8 ppm and 2 ppm toxaphene estimates of toxaphene-like material for salmonids and non-salmonids by their respective annual harvests of 60 million and 25 million pounds yields an estimated average toxaphene-like level of 6.2 ppm for the total U.S. harvest of Great Lakes table fish.

Clearly, levels are lake- and species- dependent and residue levels in local catches may far exceed 6 ppm. Clearly, too, there is need for state-of-the-art laboratory measurements of toxaphene in all the salmonid species harvested from the Great Lakes.

2) Consumption Profile

No studies which directly correlate consumption and toxaphene-like residues in the Great Lakes area were available to the Agency. However, studies correlating consumption with tetrachlorodibenzo-p-dioxin (TCDD) or PCB residues were available. Because of the lipophilic character of all these compounds, it is reasonable to assume that toxaphene-like residues would be found in the same kinds of fish as PCB and TCDD residues. Therefore, consumption data for the PCB and TCDD studies were used to assess consumption patterns of these materials.

In a 1973 PCB survey for FDA of 161 adults who regularly consumed Lake Michigan sport fish (FDA, 1973), it was found that 105 consumed more than 24 pound of fish a year, but no more than one meal per week[20/]; 37 ate six pounds or less; and 19 consumed an intermediate amount. Based on the survey results, the investigators concluded that sport fishing represents an uncontrolled source of contaminated fish for distribution and human consumption. Moreover, exposure is not limited to the fishing season because fresh caught sport fish were preserved, frozen or canned for use throughout the year.

[20/] Recommended maximum consumption by Michigan Department of Public Health.

Using catch data for trout and salmon (popular sport species likely to be contaminated with PCB) and information on the number of licensed fishermen, the same investigators also calculated that each fisherman obtains 36 pounds of Lake Michigan fish per year (3/4 pound per week) for consumption. This is over three times the reported National per capita consumption of fish from commercial sources (11.8 pounds).

In a second FDA analysis relating to TCDD (Cordle, 1981), fish consumption data for the eight Great Lakes states[21] were extracted from a national survey. From these data, mean fish consumption of all species and of a select group of species (indigenous to the Great Lakes and currently being analyzed for TCDD), in grams per day, was calculated. On the basis of the proportion of individuals in the sample population and 1970 census figures, roughly 17 million people in the eight states could be expected to consume the selected species of fish. The fish consumption data indicate that the mean daily consumption of the selected species is 7.67 grams/day, with a range of 0.1 - 160.23 grams/day; the mean daily consumption for all fish species is 20.24 grams/day, with a range of 0.3 - 201.37 grams/day.[22]

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[21] Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania, and Wisconsin.

[22]

	grams/day 90th Percentile	99th Percentile
All fish species:	41.69	92.28
Selected species:	15.70	36.83

The mean daily consumption figure from this analysis (7.67 grams/day = 6.2 pounds/year) is comparable to the lowest consumption group from the sport fish survey ($\leq$ 6 pounds/year), suggesting that consumers of sport fish may eat more fish annually than the average consumer.

3) Exposure Estimate

The residue and consumption information discussed above clearly indicates that exposure to toxaphene or toxaphene-like compounds is possible for a sizable subset of the 17 million people in the Great Lakes area who consume certain kinds of fresh fish. Sport fishermen could generally consume higher than average levels of fish species likely to be contaminated by toxaphene-like materials. Although much of the sport fishing in the Great Lakes area is seasonal, exposure to contaminated fish may extend throughout the year as a result of consumption of frozen or preserved fish.

The following assumptions, based in part on the consumption and residue information discussed above, were used by the Agency in developing an exposure estimate for high fish consumers in the Great Lakes area.

1-3. Same as for Mississippi Delta analysis.

4. Annual fish consumption is 24 pounds.

5. Fish are consumed once a week (0.46 lb/meal)

6. Fish are contaminated with 6 ppm toxaphene and not other toxaphene-like materials.[23]

Under the conditions described above, it is estimated that certain high fish consumers in the Great Lakes area could receive exposure of 2.5×10^{-3} mg/kg/day to these materials from the consumption of fish alone. Because of the wide range of residue values and variability among species and lakes, this estimate may over- or underestimate the actual exposure of a given individual. However, it is clear that exposure from other sources will only increase total exposure to levels above those attributable to contaminated fish above.

3. Occupational Exposure to Toxaphene

This section of the Decision Document evaluates potential occupational exposure resulting from the use of toxaphene. The Agency has identified human populations occupationally exposed to toxaphene and has identified the type and probable extent of their exposure. In this analysis, only two avenues of exposure are considered: respiratory and dermal. However, individuals occupationally exposed to toxaphene are also subject to the same types and amounts of nonoccupational exposure as members of the general population. Additionally, it is assumed for purposes of a worst case analyses that all exposures are at the medium level, no protective clothing or equipment is utilized, exposure occurs over a work lifetime and risks are estimated at the 95% upper confidence levels.

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[23] Median value from residue data discussed in IV.B.2.b. 1), assuming 70% of the catch made up of trout and salmon, and 30% made up of nonsalmonid table fish.

The Agency routinely uses human exposure date generated from other pesticide monitoring studies in the assessment of exposure when faced with a lack of data for the pesticide of interest. The selection of surrogate data is based on similarity of formulation, use pattern, and application technique, since the general perception is that these factors are dominant in determining exposure during application (Severn, 1981).

Toxaphene is applied aerially and by ground equipment to crops. This assessment will consider the applications of toxaphene to cotton, sorghum, wheat, peanuts, corn, and soybeans. These uses were identified to the Agency by the United States Department of Agriculture as the primary agricultural uses. Use patterns on minor toxaphene crops are similar to that for these crops, and none of the application practices for the minor uses are known to pose special additional hazards. Toxaphene is also applied to livestock, primarily by spray or as a dip. Although toxaphene is available as a dust, wettable powder, or emulsifiable concentrate, the primary formulation used is the emulsifiable concentrate.

Because of the limitations of available data and the resulting necessity to resort to assumptions for many of the key elements of occupational exposure estimates, considerable uncertainty is associated with these estimates. The Agency is not aware of any toxaphene exposure studies; therefore, studies with surrogate chemicals were used to develop these estimates. In addition, the duration of exposure is a major variable which was difficult, if not impossible, to ascertain.

Toxaphene is applied aerially by commercial applicators. In order to determine annual exposure, the Agency assumes that an aerial applicator applies toxaphene for a specified length of time limited to the time the pest is active and being treated.

Toxaphene is applied by ground rigs primarily by private farmers. The Agency assumes that an applicator will apply toxaphene to his own farm and uses the average or median size farm to estimate annual exposure of ground boom applicators to toxaphene.

Toxaphene is used for livestock treatment either as a spray or dip for the animals. The Agency has also recently become aware of a spray-dip machine method for treating livestock, which involves spray treatment of the animal in a totally enclosed portable unit (USDA, 1975). Although no information is available to the Agency on which to base a quantitative estimate of occupational exposure from the dip and spray-dip machine methods, it is reasonable to assume that some exposure does take place. For example, dip and spray-dip mixers would get comparable exposure to mixers for other methods involving similar mixing procedures. However, logic suggests that exposure from the dip and spray-dip machine methods would not exceed that received during the spray method, and may even be less. Therefore, the exposure assessment for livestock use of toxaphene will be done for the spraying method.

a. Assumptions Used in This Analysis

The following general assumptions were used by the Agency in developing its exposure estimates.

1. No protective clothing is worn during application. Protective clothing is not normally worn while applying toxaphene to soybeans as a herbicide (Petrie, 1982). [If protective clothing were worn, the Agency estimates that dermal exposures would be reduced by at least 80% and respiratory exposures would be reduced during loading by 90%, assuming use of a respirator (Kozak, 1980).]

2. Emulsifiable concentrate is used in the application. Toxaphene emulsifiable concentrates are commonly found in 2:1 mixtures of toxaphene to methyl parathion. Since methyl

parathion is a restricted use chemical, it is likely that protective clothing will be worn when this mixture is applied and exposure will be reduced as described in assumption 1 above. Respirators are likely to be worn only by mixer/loaders.

3. The pulmonary absorption rate is 100 percent; the dermal absorption rate is 10 percent. These rates are logical.

4. An applicator weighs 70 Kg.

In addition to the above general assumptions, the Agency used other assumptions which relate to specific use patterns. These specific assumptions are discussed on a use-by-use basis in Appendix C.

b. Aerial Application

Toxaphene is aerially applied to cotton, sorghum, wheat, peanuts, and soybeans primarily as an emulsifiable concentrate, either alone or in combination with other substances. Number of annual applications, application rates, and other use-conditions vary depending upon the situation. A "typical" application rate is 2 pounds per acre.

No toxaphene study was available to the Agency from which to estimate exposure to aerial mixer/loaders, pilots, and flaggers during aerial application. However, surrogate studies (Peoples, 1981; Atallah, et al., 1982) using DEF and EPN (respectively) during aerial application were available.

Both DEF and EPN are emulsifiable concentrates as is toxaphene, and EPN is an insecticide, which is the primary classification for toxaphene. Using both studies, the Agency estimated a range of average dermal and respiratory exposures for mixer/loaders, pilots and flaggers. These average values are given in Table IV-6.

c. Ground Rig Application

Toxaphene is applied to cotton, soybeans, peanuts, sorghum, wheat and corn primarily as an emulsifiable concentrate by boom sprayers. The sprayer may be mounted on a tractor, incorporated into a high clearance self propelled unit, or drawn by a tractor. Nozzle arrangements and pressures vary depending on the crop-pest situation and the sprayer unit. The "typical" application rate is 2 pounds active ingredient per acre in 15 to 20 gallons of water.

No ground application exposure study for toxaphene is available to the Agency. However, published surrogate ground rig studies were available. Wolfe (Wolfe, et al., 1967) sprayed the insecticide parathion (0.09% at 0.5 lbs. a.i./acre) using a tractor-mounted ground boom sprayer in row crops. Mean dermal and respiratory worker (n=7) exposures of 4.7 and <0.01 mg/hr, respectively, were found. In the same paper, parathion formulated as a 1% dust was applied to crops using a tractor-mounted boom duster in row-crops. Mean worker (n=33) dermal and respiratory exposures were 8.8

Table IV-6. Average Daily Exposures for Aerial Application[1]

	Dermal (mg/day)*/	Respiratory (mg/day)*/
Mixer/Loaders	3.9-13.5	0.09-0.55
Pilots	1.3-8.6	0.07-0.35
Flaggers	14.5-73.6	1.9-2.0

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*/ Adjustments have been made for the difference in work days between DEF (7 hrs.), EPN (8 hrs) and toxaphene (5 hrs.): DEF exposure (mg/day) x 5/7 = toxaphene exposure.

[1] These figures were derived from the studies by Peoples, 1981 and Atallah, et al., 1982, with the adjustments noted above. In all cases, except for flaggers, the lower values correspond to the EPN (Atallah) study.

and 0.7 mg/hr, respectively. In another study (Staiff, et al., 1975), the herbicide paraquat (0.14% formulated as a liquid concentrate and used at the rate of 1 lb a.i./acre) was sprayed using tractor mounted low-boom spray equipment in orchards. Mean workers (n=20) dermal and respiratory exposures were found to be 0.4 and <0.001 mg/hr, respectively. Atallah (Atallah, et al., 1982) sprayed the insecticide EPN (1.8% at the rate of 1 lb. a.i./acre) using ground rigs on cotton. Mean dermal and respiratory exposures (n=2) were found to be 0.9 and 0.005 mg/hr.

Because of the wide range of exposure values reported for ground equipment, the Agency will use the exposure values found for EPN (i.e., 0.9 and 0.005 mg/hr). EPN was applied as an emulsifiable concentrate at a use dilution rate comparable to the one used in toxaphene applications.

d. Livestock Application

Toxaphene is applied to livestock as a dip or spray, or in a spray-dip machine or "backrubber" for control of horseflies, faceflies, lice, mites, ticks and scabies. As previously indicated, greatest applicator exposure is expected to result from the spray method. In a "typical" spray application, toxaphene is applied in a 0.5% solution at 250 psi pressure.

No toxaphene study was available to the Agency from which to estimate exposure to applicators from livestock treatments. However, exposure estimates for the spraying of toxaphene on livestock are comparable to exposures during power hand gun spraying of fruit orchards from a portable machine. Using 0.03% dieldrin, Wolfe et al. (1967) found dermal exposure of 15 mg/hr and respiratory exposure of 0.03 mg/hr. No protective clothing was worn in the study. Using these figures, the Agency estimated occupational exposure resulting from toxaphene treatment of livestock.

e. Exposure Estimates

Using the information and assumptions given above and in Appendix C, the Agency has developed estimates of occupational exposure for the various types of personnel likely to be exposed to toxaphene. These estimates, organized by use-pattern, are given in Table IV-7. Based on these results, it is clear that, as a class, flaggers are likely to have the greatest exposure (0.05 - 5.3 mg/kg/yr), whereas ground rig applicators have the least potential for exposure (0.01 - 0.2 mg/kg/yr).

Table IV-7. Occupational Exposure to Toxaphene

(No Protective Clothing Assumed)

Crop/Personnel	Hourly Exposure (mg/hr)		Exposure Duration (hrs/year)	Annual Exposure (mg/year)		Annual Dosage[1/] (mg/kg/year)		
	Dermal	Respiratory		Dermal	Respiratory	Dermal	Respiratory	Total
Cotton								
Aerial Application								
Pilot	0.26-1.7	0.01-0.07	100-200	26-340	1-14	0.04-0.5	0.01-0.2	0.05-0.7
Aerial Mixer	0.78-2.7	0.02-0.1	100-200	78-540	2-20	0.1-0.8	0.03-0.3	0.13-1.1
Flagger	2.9-14.7	0.4-0.4	100-200	290-2940	40-80	0.4-4.2	0.6-1.1	1.0-5.3
Ground rig	0.9	0.005	84-174	76-157	0.4-0.9	0.1-0.2	<0.01	0.1-0.2
Soybeans								
Aerial Application								
Pilot	0.26-1.7	0.01-0.07	10-100	2.6-170	0.1-7	<0.01-0.2	<0.01-0.1	<0.01-0.3
Aerial Mixer	0.78-2.7	0.02-0.1	10-100	7.8-270	0.2-10	0.01-0.4	<0.01-0.1	0.01-0.5
Flagger	2.9-14.7	0.4-0.4	10-100	29-1470	4-40	0.04-2.1	0.06-0.6	0.1-2.7
Ground rig	0.9	0.005	8.4-41.6	7.6-37.4	0.04-0.2	0.01-0.05	<0.01	0.01-0.05
Peanuts								
Aerial Application								
Pilot	0.26-1.7	0.01-0.07	5	1.3-8.5	0.05-0.35	<0.01-0.01	<0.01	<0.01-0.01
Aerial Mixer	0.78-2.7	0.02-0.01	5	3.9-13.5	0.1-0.5	0.01-0.02	<0.01	0.01-0.02
Flagger	2.9-14.7	0.4-0.4	5	14.5-73.5	2-2	0.02-0.1	0.03	0.05-0.13
Ground rig	0.9	0.005	6-24	5.4-21.6	0.03-0.1	0.01-0.03	<0.01	0.01-0.03

Table IV-7 (Continued)

(No Protective Clothing Assumed)

Crop/Personnel	Hourly Exposure (mg/hr)		Exposure Duration (hrs/year)	Annual Exposure (mg/year)		Annual Dosage[1/] (mg/kg/year)		
	Dermal	Respiratory		Dermal	Respiratory	Dermal	Respiratory	Total
Sorghum								
Aerial Application								
Pilot	0.26-1.7	0.01-0.07	5	1.3-8.5	0.05-0.35	<0.01-0.01	<0.01	<0.01-0.01
Aerial Mixer	0.78-2.7	0.02-0.1	5	3.9-13.5	0.1-0.5	0.01-0.02	<0.01	0.01-0.02
Flagger	2.9-14.7	0.4-0.4	5	14.5-73.5	2-2	0.02-0.1	0.03	0.05-0.13
Ground rig	0.9	0.005	5-9	4.5-8.1	0.02-0.04	0.01	<0.01	0.01
Wheat								
Aerial Application								
Pilot	0.26-1.7	0.01-0.07	5	1.3-8.5	0.05-0.35	<0.01-0.01	<0.01	<0.01-0.01
Aerial Mixer	0.78-2.7	0.02-0.1	5	3.9-13.5	0.1-0.5	0.01-0.02	<0.01	0.01-0.02
Flagger	2.9-14.7	0.4-0.4	5	14.5-73.5	2-2	0.02-0.1	<0.03	0.05-0.13
Ground rig	0.9	0.005	8-15	7.2-13.5	0.04-0.08	0.01-0.02	<0.01	0.01-0.02
Corn								
Ground rig	0.9	0.005	13.6-27.4	12.2-24.7	0.07-0.14	0.02-0.04	<0.01	0.02-0.04
Livestock								
Spraying	250	0.5	9.9	2475	5.0	3.5	0.07	3.6

1/ Assume 10 percent dermal absorption and 100 percent pulmonary absorption. Assume 70 kg person.

C. Human Quantitative Risk Assessment - Oncogenicity

In the following section, the Agency presents theoretical estimates of cancer risk from the use of toxaphene: 1) to the general population from exposure to toxaphene residues in contaminated food and water; 2) to regional populations in the Mississippi Delta and Great Lakes areas from consumption of toxaphene-contaminated fish; and 3) to workers exposed during application of toxaphene. Where feasible, the Agency has incorporated the available appropriate exposure data into estimates of the lifetime probability of cancer due to toxaphene exposure for these groups.[24]

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[24] The Interim Cancer Guidelines state that when a chemical is judged to be a potential human carcinogen, the Agency will make estimates of its possible impact on public health at anticipated levels of exposure. These guidelines also recognize that the available techniques for assessing the magnitude of cancer risk to human populations based on animal data are at best very crude; this is due, among other causes, to uncertainties in the extrapolation of dose-response data to very low dose levels and to differences in levels of susceptibility of animals and humans. In addition, the actual chance of people receiving these worst case exposure levels and the upper limit nature of the risk models used make any of these estimates crude estimates of maximum risk, given our current capabilities to model such effects.

The Agency's risk estimates for toxaphene are based on the development of hepatocellular carcinoma and neoplastic nodules in $B6C3F_1$ male mice in the Litton Bionetics bioassay (EPA, 1978), using the multistage model to develop an upper limit carcinogenic potency factor for humans, of $q^* = 1.131 \times (\text{mg/kg/day})^{-1}$. Since lifetime animal studies were used to make these risk estimates, the probability of cancer in humans is estimated as a lifetime probability, and, therefore, should be interpreted as an index or "mathematical" expectation rather than a "clinical" expectation. The Agency is currently re-evaluating the significance of mouse liver tumors resulting from exposure to other pesticides when compared with the incidence in control animals. In this regard, the quantitative risk estimates based on these liver tumors and assumptions that humans are approximately an order of magnitude more sensitive than mice probably overstate the actual risk. The estimates used in this section are consistent with current risk assessment methods, and are based on current Agency knowledge and worst case assumptions.

1. Cancer Risk to the General Population

Some people are potentially at risk from toxaphene due to direct exposure to toxaphene residues or through the consumption of contaminated foods and water, but this risk varies substantially with geography and dietary habits. When, as here, extensive monitoring data are not available, one approach to estimating exposure to contaminated foods is to extrapolate from existing tolerance levels. In the case of toxaphene, this approach is not particularly helpful because 1) all acreage is not treated and total consumption of a given food is unlikely to be from contaminated sources; and 2) toxaphene tolerances were set years ago and may not reflect real residues. Therefore, dietary exposure estimates relying on toxaphene tolerances may not reflect actual food residues. However, indications from government monitoring programs are that toxaphene-like residues do occur in certain food stuffs, and are sometimes found at levels at or higher than the tolerance limits. Finally, as previously indicated, no attempt has been made to quantify human exposure or risk from the consumption of toxaphene-contaminated water.

Notwithstanding the difficulty in reliably quantifying exposure to toxaphene from foods and water, it is clear that certain members of the general population are potentially at some risk from these sources. Because of toxaphene's environmental transport mechanisms and the very real possibility of contaminated fish in the marketplace, this potential risk may extend to populations outside of toxaphene use areas.

2. Potential Cancer Risk to Regional Populations from Consumption of Contaminated Fish

Specific estimates of dietary exposure from contaminated fish alone and resulting cancer risk were calculated for persons living in the Mississippi Delta and Great Lakes areas of the United States presuming Great Lakes residues are indeed toxaphene. These areas were selected for detailed analysis because of the availability of information documenting the extensive contamination of fish in the areas with toxaphene and/or toxaphene-like residues and the high fish consumption patterns of the populations in these areas (see Chapter IV-B-2). Based on fish consumption alone, the estimated dietary exposure of the Mississippi Delta population is 1.3×10^{-2} mg/kg/day, therefore the estimated cancer risk index is 1.4×10^{-2}. For the Great Lakes population, if the material is indeed toxaphene, the calculated dietary exposure and cancer risk index are 2.6×10^{-3} mg/kg/day and 2.9×10^{-3}, respectively.

3. Potential Cancer Risk to Toxaphene Applicators

Toxaphene applicators are likely to experience greater total exposure and concurrent risk of cancer than the populations previously discussed. Based on worst case daily exposure estimates ranging from $<3 \times 10^{-5}$ to 3×10^{-2} mg/kg/day (see Appendix D, Table D-3), the upper limit on worst case lifetime relative probability of cancer due to combined dermal and inhalation exposure to toxaphene was calculated for each of the applicator populations by specific use. These results, given in Table IV-8, indicate maximum worst case potential relative cancer risks to toxaphene applicators ranging from $<3 \times 10^{-5}$ for some ground applicators to 2×10^{-2} for certain flaggers. It is emphasized that many persons in the occupational subpopulation may also be exposed to toxaphene from other sources. It is further emphasized that such cancer risk levels are statistical estimates of the upper limit of a relative risk index under worst case conditions (e.g., high exposure and maximum uptake) and are not estimates of actual clinical levels expected to be found in the human population.

Table IV-8. Lifetime Probability of Cancer to Toxaphene Applicators*/

(No Protective Clothing Assumed)

Crop/Personnel	Dermal Risk	Respiratory Risk	Total Risk Index
Cotton			
Aerial Application			
Pilot	6.2×10^{-5} to 7.75×10^{-4}	1.55×10^{-5} to 3.1×10^{-5}	7.75×10^{-5} to 1.09×10^{-4}
Aerial Mixer	1.19×10^{-4} to 1.24×10^{-3}	4.65×10^{-5} to 4.65×10^{-4}	8.06×10^{-4} to 1.71×10^{-3}
Flagger	6.2×10^{-4} to 6.5×10^{-3}	9.27×10^{-4} to 1.7×10^{-2}	1.55×10^{-3} to 2.35×10^{-2}
Ground rig	1.19×10^{-4} to 3.1×10^{-4}	$<1.55 \times 10^{-5}$	1.19×10^{-4} to 3.1×10^{-4}
Soybeans			
Aerial Application			
Pilot	$<1.55 \times 10^{-5}$ to 3.1×10^{-5}	$<1.55 \times 10^{-5}$ to 3.1×10^{-5}	$<3.1 \times 10^{-5}$ to 6.2×10^{-5}
Aerial Mixer	$<1.55 \times 10^{-5}$ to 6.2×10^{-4}	$<1.55 \times 10^{-5}$ to 3.1×10^{-5}	$<3.1 \times 10^{-5}$ to 6.2×10^{-5}
Flagger	6.2×10^{-5} to 3.2×10^{-3}	9.27×10^{-5} to 9.27×10^{-4}	1.55×10^{-4} to 7.43×10^{-3}
Ground rig	1.55×10^{-5} to 7.75×10^{-5}	$<1.55 \times 10^{-5}$	$<3.1 \times 10^{-5}$ to $<9.3 \times 10^{-5}$
Peanuts			
Aerial Application			
Pilot	$<1.55 \times 10^{-5}$ to 3.1×10^{-5}	$<1.55 \times 10^{-5}$	$<3.1 \times 10^{-5}$
Aerial Mixer	$<1.55 \times 10^{-5}$ to 6.2×10^{-4}	$<1.55 \times 10^{-5}$	$<3.1 \times 10^{-5}$
Flagger	6.2×10^{-5} to 3.25×10^{-3}	4.65×10^{-5}	1.09×10^{-4} to 3.29×10^{-3}
Ground rig	1.55×10^{-5} to 7.75×10^{-5}	$<1.55 \times 105$	$<3.1 \times 10^{-5}$ to $<9.3 \times 10^{-5}$

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*/ The upper 95% confidence limit on the cancer risk is obtained by multiplying the carcinogenic potency factor, $q^* = 1.131\ (\text{mg/kg/day})^{-1}$ by the calculated lifetime exposure in mg/kg/day. The applicator is assumed to be exposed 35 of a 70 year lifetime.

Table IV-8. (Continued)

(No Protective Clothing Assumed)

Crop/Personnel	Dermal Risk	Respiratory Risk	Total Risk Index
Sorghum			
Aerial Application			
Pilot	$<1.55 \times 10^{-5}$ to 1.55×10^{-5}	$<1.55 \times 10^{-5}$	$<3.1 \times 10^{-5}$
Aerial Mixer	1.55×10^{-5} to 3.1×10^{-5}	$<1.55 \times 10^{-5}$	3.1×10^{-5}
Flagger	3.1×10^{-5} to 1.55×10^{-4}	4.65×10^{-5}	7.75×10^{-5} to 2.01×10^{-5}
Ground rig	1.55×10^{-5}	$<1.55 \times 10^{-5}$	$<3.1 \times 10^{-5}$
Wheat			
Aerial Application			
Pilot	$<1.55 \times 10^{-5}$ to 1.55×10^{-5}	$<1.55 \times 10^{-5}$	$<3.1 \times 10^{-5}$ to 3.1×10^{-5}
Aerial Mixer	1.55×10^{-5} to 3.1×10^{-5}	$<1.55 \times 10^{-5}$	5.2×10^{-5} to 7.75×10^{-5}
Flagger	3.1×10^{-5} to 1.55×10^{-4}	4.65×10^{-5}	$<4.65 \times 10^{-5}$ to 1.55×10^{-4}
Ground rig	1.55×0^{-5} to 3.1×10^{-5}	$<1.55 \times 10^{-5}$	$<3.1 \times 10^{-5}$ to $<4.65 \times 10^{-5}$
Corn			
Ground rig	3.1×10^{-5} to 6.2×10^{-5}	1.55×10^{-5}	4.65×10^{-5} to 7.75×10^{-5}
Livestock			
Spraying	5.42×10^{-3}	1.09×10^{-4}	5.53×10^{-3}

4. Summary

Certain human populations have an increased risk of cancer because of their exposure to toxaphene. Although the risk to the general population attributable to the consumption of contaminated food and water is not readily quantifiable, toxaphene residues have been detected in food and water sources. Moreover, the risk index for certain regional populations where high consumption of contaminated fish is likely, is expected to be high, based on fish consumption alone, as is the worst case risk index for certain toxaphene applicators.

V. BENEFIT ANALYSIS OF TOXAPHENE

In this Chapter, the Agency examines the projected economic impacts of the cancellation of toxaphene. The analyses take into consideration the availability, cost and efficacy of alternative chemicals.

A. Introduction

Toxaphene is registered as an insecticide and herbicide with a wide variety of use patterns on about 300 sites. It is estimated that approximately 33 million pounds of toxaphene were applied to cropland and livestock in 1976; of that usage, 22 million pounds were applied to cotton. Since 1976, toxaphene annual usage on cotton has declined to an estimated 2.5 million pounds or less and total annual usage has declined to approximately 16 million pounds.

In 1978, the USDA/State Assessment Team on Toxaphene in cooperation with the Environmental Protection Agency estimated the economic benefits of toxaphene use as an insecticide on cotton, soybeans, sorghum, peanuts, wheat and beef cattle (USDA/State Assessment Team Report). The estimates of acres or heads of cattle treated, the identification of alternatives, and the estimates of comparative performance of alternative insecticides in the USDA/State Assessment Team Analysis were based primarily on the Biological Survey for Toxaphene Assessment (USDA, 1977.

1976 Biological Survey for Toxaphene Assessment, Completed Survey Forms) and preliminary results from the 1976 National Pesticide Usage Survey (USDA, ERS, 1977. 1976 National Pesticide Usage Survey). The alternatives which were chosen for analysis as substitutes for toxaphene were selected based on cost, efficacy, and availability. Prices were obtained from published sources and from discussions with manufacturers' representatives and distributors.

Using these data, a partial budgeting method was employed to assess the economic impacts of a toxaphene cancellation in the 1977 growing season. The partial budgeting methodology measures the change in the cost of pest control and the effect on returns which would be associated with substituting alternative pesticides, while holding all other budgetary inputs constant.

The economic estimates developed by USDA in 1978 are combined with updated toxaphene usage data and information on newly registered alternatives to indicate the economic significance of toxaphene's current use as an insecticide on wheat, sorghum, peanuts, soybeans, and beef cattle.

More recently developed data were used in the 1980 Environmental Protection Agency analysis of toxaphene use on cotton. Historical and current (1979) usage information on cotton insecticides, efficacy data presented to EPA by

USDA in support of Section 18 specific exemptions for new cotton insecticides (USDA, 1977)[25], small plot field test data (1970-1979), and 1979 cotton insecticide prices were used to estimate the economic impacts of a toxaphene cancellation on cotton. The analysis concluded that toxaphene's application to cotton would be minimal by the mid-1980's.

In addition to toxaphene's insecticidal uses, it is also applied to soybeans and peanuts as an herbicide to control sicklepod. In early 1980, several states granted Section 24c registrations for the use of toxaphene as an herbicide on peanuts and soybeans. The economic impact of the cancellation of toxaphene's herbicide uses was analyzed by the Agency in 1982.

Estimates of economic impacts associated with the cancellation of toxaphene's major uses are summarized in Table V-1.

25/ United States Department of Agriculture. 1977. The Bollworm and Tobacco Budworm on Cotton. Status of Insecticides and Other Methods of Control for 1977, Washington, DC, 26 January. Submitted to the Environmental Protection Agency in support of Section 18 Specific Exemption to Registration for permethrin, fenvalerate, and sulprofos.

Table V-1.
Economic Impacts Associated with the Cancellation of Toxaphene Major Uses

Site/Pest	Use Pattern[1/]	Extent of Use 1,000 lbs	Units Treated (acre treatments or head of cattle)	Equally Efficacious Alternatives Available	Economic Impacts	
					User	Market/Consumer
Cotton						
Heliothis	I	2,500	1,000,000	Yes	None expected except in isolated cases	None
Wheat	I	1,120	560,000			
Grasshopper		NA[5/]	NA	Uncertain[6/]	Potentially small to moderate possible yield loss and increased control costs	None
		—				
Armyworm		NA	NA	Uncertain[6/]	Minimal	None
Soybeans						
Insects[2/]	I	1,590	795,000	Yes	Minimal	None
Soybeans						
Sicklepod	H	3,960	990,000	No	\$6.62-\$43.84 per acre \$8.8-\$19.7 million aggregate costs.[8/] Includes change in chemical costs and yield and quality losses.	Increased soybean prices, domestic market increases prices \$8.7 million[8/]
Peanuts						
Insects[3/]	I	160	80,000	Yes	Minimal	None
Sorghum						
Insects[4/]	I	165	110,000	Yes	Minimal	None
Beef Cattle		1,986	16,893,000			
Lice	I	NA	5,932,000	Yes	Minimal	None
Face Fly	I	NA	5,836,000	Yes	Minimal	None
Horn Fly	I	NA	3,471,000	Yes	Minimal	None
Tick	I	NA	755,000	Yes	Minimal	None
Mite (scabies)	I	NA	899,000	No[7/]	Moderate increased control costs and possible increased mortality of cattle[9/]	None

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1/ I-Insecticide; H-Herbicide
2/ Includes armyworms, bean leaf beetles, green cloverworms, and grasshoppers.
3/ Includes armyworms, leafhoppers, thips, and velvetbean caterpillars.
4/ Includes armyworms, grasshoppers, and green cloverworms.
5/ Information not available.
6/ 1976 alternatives did not provide equal efficacy, efficacy of new registrations not evaluated.
7/ Comaphos and prolate[R] provide equal level of control with increased number of treatments; however, they are more toxic to cattle and may result in livestock deaths. Lindane has potential application problems and an extended pre-slaughter interval.
8/ 1982 dollars
9/ Does not include possible increased costs of using toxaphene due to required compliance with RCRA for disposal of spent dip vat waste.

B. Cotton (Insecticidal Applications)

Toxaphene applied in combination with methyl parathion has been widely used for control of cotton pests, since the early 1950's. Other formulations include toxaphene/ methyl parathion/ EPN, and toxaphene/ethyl parathion. Between 1964 and 1976, toxaphene usage on cotton remained at approximately 27-28 million pounds of active ingredient annually (Eichers, et al., 1978; Andrilinas, 1974; Eichers, et al. 1970; Eichers, et al., 1968).

Bollworms and budworms (Heliothis zea and Heliothis virescens) are two major pests of cotton. The tobacco budworm became a critical pest on cotton in the mid-1970's (Roussel, 1976). There were three main reasons: 1) an increase in the level of resistance by the tobacco budworm to insecticides registered at that time including toxaphene (USDA, 1977), 2) the withdrawal of insecticides, such as aldrin/dieldrin, as a result of regulatory action, and the temporary voluntary withdrawal of chlordimeform, and 3) an increase in the population of the tobacco budworm due to increased resistance to registered pesticides and the destruction of natural predators.

Due to increased tobacco budworm pressures and the ineffectiveness of registered insecticides for controlling budworm/bollworm infestations, in 1977 EPA granted Section 18 specific exemptions under FIFRA to the states of Alabama, Arizona, Arkansas, California, Georgia, Louisiana, Mississippi, North Carolina, Oklahoma, South Carolina, and Texas to apply three new, and at that time unregistered, insecticides. The new insecticides included two pyrethroids, fenvalerate (Pydrin^R) and permethrin (Ambush^R and Pounce^R), and an organophosphate, sulprofos (Bolstar^R). Section 18 emergency exemptions were again granted for these chemicals in 1978 for the same states as above, plus Florida, New Mexico and Tennessee. In 1979, these chemicals were conditionally registered for use on cotton.

The introduction of these new insecticides for control of Heliothis on cotton has significantly reduced the application of previously utilized compounds. It is estimated that as much as 30 percent of the cotton acreage harvested in 1976 may have been treated with toxaphene; however, more recently usage has dropped to a maximum of 5 percent of U.S. cotton acreage and 3 percent or less of total cotton insecticide acre treatments. To a large extent since 1978, usage of the pyrethroids and sulprofos has been substituted for the application of toxaphene + methyl parathion.[26]

In addition to the application of the toxaphene + methyl parathion combination and the recently registered new insecticides Bolstar and the synthetic pyrethroids, EPN, chlordimeform, methomyl, methyl parathion, monocrotophos, and acephate are also widely used either alone or in combination for Heliothis control on cotton.

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[26] Toxaphene is formulated in combination with methyl parathion.

The available efficacy and performance data indicate that yield losses should not occur from Heliothis damage if toxaphene use on cotton is cancelled. This finding is consistent with data presented to EPA in the 1977 USDA submission supporting the Section 18 specific exemptions for fenvalerate (Pydrin®), sulprofos (Bolstar®) and permethrin (Ambush®, Pounce®) (USDA, 1977), and field test data obtained by EPA and analyzed using the Binomial Sign Test which indicates superiority of several of the currently available insecticides over toxaphene + methyl parathion (Zygadlo, 1980). Superior performance of several of the insecticides suggest that substitution of these alternatives for toxaphene + methyl parathion would result in increased yields.

Although resistance is an issue of concern, projections of cotton pest resistance to the new insecticides are uncertain. However, it is clear that Heliothis has developed resistance to toxaphene and lessened the usefulness of the chemical.

The lower level of toxaphene + methyl parathion applications since the widespread introduction of sulprofos (Bolstar®), fenvalerate (Pydrin®), and permethrin (Pounce®, Ambush®) in 1979, are the best indications of toxaphene's reduced significance in cotton pest control. Although toxaphene + methyl parathion applications remain competitively priced with alternative insecticide treatments for Heliothis control, usage of toxaphene on cotton has declined substantially.

Usage of alternative insecticides over toxaphene + methyl parathion by cotton growers suggests that the alternative cotton insecticides are equally efficacious or superior to toxaphene + methyl parathion applications. If toxaphene + methyl parathion were superior or equally efficacious to alternative insecticides, competitive pricing of the product would result in continued wide usage of the product rather than the rapid decline in usage recently experienced.

Insecticide usage data combined with comparative performance and cost data indicate that the economic impacts of a toxaphene cancellation on cotton would be small. Use of chlorpyrifos (0.5 lb a.i.) instead of toxaphene + methyl parathion (2.0 lb a.i. toxaphene + 1.0 lb a.i. methyl parathion) can be expected to result in increased chemical costs of $1.12 per acre-treatment (1980 pesticide prices and dollars). Use of sulprofos (1.5 lb a.i.) instead of toxaphene + methyl parathion (2.0 lb a.i. toxaphene + 1.0 lb a.i. methyl parathion) can be expected to increase the chemical costs by $6.25 per acre-treatment (1980 chemical prices and dollars). However, in addition to chlorpyrifos (Lorsban), EPN (currently under RPAR review: PD1 was published 1/27/78) + methyl parathion, an alternative insecticide which is widely used, is also available in the same price range as toxaphene + methyl parathion. Furthermore, if it can be assumed that toxaphene + methyl parathion is used at the higher recommended application rate (due to resistance problems and lower levels of performance) and that alternative insecticides can be applied at the lower end of their recommended application rates (due to superior performance), most of the alternative insecticides are competitively priced to toxaphene + methyl parathion.

The most likely scenario in the mid-1980's for toxaphene is that it would be a minor factor in cotton production. Other chemicals are currently available which provide equally efficacious or superior control at competitive prices and should such alternatives continue to be available in the 1980's, it is possible that toxaphene use would decline to near zero. In a typical year it might account for a maximum of 1-2 percent of U.S. cotton acreage and even less of total cotton insecticide treatments. Although the economic impacts of a toxaphene cancellation are not quantitatively estimated here[27/], economic impacts are projected to be minimal. User impacts might be experienced in isolated circumstances or limited areas where

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[27/] To quantitatively estimate economic impacts, typical cotton pest control strategies using toxaphene + methyl parathion and alternative insecticides must be identified. Furthermore, the resultant yield impacts with alternative control strategies at varying levels of pest infestation must be quantified. Due to the availability of alternatives which are more efficacious than toxaphene, cotton production in the aggregate could increase in the event of a toxaphene cancellation.

toxaphene is the chemical of choice due to prior use patterns. However, due to the general availability of equally efficacious and/or superior alternatives, cotton production losses are not anticipated. Significant economic impacts would not be expected at either the market or consumer level.

The economic impact analysis of the cancellation of toxaphene on cotton has the following limitations:

1) The analysis focuses exclusively on the use of toxaphene + methyl parathion applications for Heliothis spp. control. However, control of this pest was identified as the major use of toxaphene by the National Cotton Council of America and the USDA/State Assessment Team on Toxaphene (National Cotton Council of America, 1977; USDA/State Assessment Team on Toxaphene, 1978).

2) Comparative performance of alternative insecticides is not evaluated at the regional level due to an insufficient number of small plot field experiments. If more research data had been available, a more refined analysis evaluating efficacy data at the regional level could have been performed.

3) Projections for pest resistance to the pyrethroids are uncertain. However, it is clear that pests

have developed resistance to toxaphene and reduced its usefulness. Scenarios identifying possible pest resistance to other cotton insecticides in the 1980's have not yet been developed.

4) Continued availability of the pyrethroids, some of which are now conditionally registered, is dependent upon receipt and analysis by EPA of certain long term testing.

In the event that use patterns of toxaphene return to pre-1978 conditions, the economic effect of cancellation would still be minor since equally efficacious alternatives other than the pyrethroids exist. Yield losses would not be anticipated; however, alternative insecticides might be more expensive than the toxaphene + methyl parathion formulation.

C. Beef Cattle (Insecticidal Applications)

On January 1, 1977, approximately 108.0 million beef cattle and calves were on hand (USDA 1977). Of this number approximately 16 percent were treated with 1.9 million pounds active ingredient toxaphene for lice, face fly, horn fly, mite (scabies), or tick control at least once during 1976. Of the estimated 16.9 million beef cattle treated, Texas, Missouri, and Kansas had the largest number of animals treated, 2.3, 2.0, and 1.7 million animals, respectively.

Of the 16.9 million beef cattle treated with toxaphene in 1976, approximately 35 percent were treated for face fly control. The USDA 1978 analysis identified alternative chemicals which were registered in 1976 for control of face fly. Of the chemical treatments, Ciodrin® + DDVP was estimated to cost less per animal than toxaphene ($0.560 per animal versus toxaphene costs of $0.606, 1977 dollars). In addition, since the 1976 survey, several new pesticides have been registered which are efficacious for face fly controls. These new chemicals include: permethrin, chlorpyrifos, and, fenvalerate. Since efficacious alternatives to toxaphene are available for face fly control the economic impacts of eliminating toxaphene for this use are considered minimal.

Approximately 35 percent of the beef cattle treated with toxaphene in 1976 were treated for lice control. The 1978 analysis estimated that the costs per animals for toxaphene treatments for lice were $0.242 (1977 dollars). Both Ronnel and coumaphos were identified as less expensive lice controls, $0.217 and $0.231 per animal respectively. In addition, since 1976 chlorpyrifos has been registered for lice control on beef cattle. Since efficacious alternatives to toxaphene are available for lice control, the economic impacts of eliminating toxaphene for this use are considered minimal.

Over 20 percent of the beef cattle treated with toxaphene in 1976 were treated for horn fly control. The 1978 analysis identified coumaphos and methoxychlor as the only efficacious alternatives. These chemicals were estimated to cost an average of 9.2 cents (1977 dollars) more per animal to apply. However, since the 1976 survey several new pesticides have been registered and are considered effective for horn fly control. These chemicals include: permethrin, chlorpyrifos, and fenvalerate. The availability of alternatives is expected to result in minimal economic impacts if toxaphene is cancelled for horn fly control.

Approximately 4 percent of the beef cattle were treated for tick control. Coumaphos and dioxathion were the alternatives identified in the USDA analysis. The substitution of these chemicals for toxaphene were expected to increase tick control costs by $0.202 (1977 pesticide costs and dollars) per animal. Since the 1976 survey permethrin, chlorpyrifos, and fenvalerate have been registered for tick control. Due to the availability of these efficacious alternatives minimal economic impacts are expected if toxaphene is cancelled for tick control.

Of the 16.9 million beef cattle treated with toxaphene in 1976, less than 900,000, or 5 percent, were treated for mite (scabies) control. Coumaphos and Prolate® were the alternatives identified in the 1978 analysis. These chemicals are considerably more expensive than toxaphene. In addition, the rates of application necessary as an acaracide are only slightly lower than levels of toxicity to the animals while toxaphene can be applied at four times the recommended application rate without inducing toxic responses. Therefore, animal mortalities would be expected to increase with the substitution of these alternatives. Since 1976, efficacious new pesticides have not been registered for scabies control. However, lindane has recently been approved by the APHIS Livestock Quarantine Program for scabies treatment of cattle. Lindane has not been used since 1970 because, although considered as efficacious as toxaphene for scabies control, it increases the pre-slaughter interval from the 28 days required after toxaphene treatment to 60 days. Further, it is reportedly difficult to maintain the proper concentration of lindane in dipping vats. Finally, there is some concern that current lindane formulations (wettable powders) may be more abrasive to pumps and equipment than the emulsifiable concentrate formulation of toxaphene.

It also should be noted that Ivermectin, a promising new animal health compound, currently is being studied as an injectable by the Food and Drug Administration (FDA). Since Ivermectin reportedly is particularly effective in controlling scabies mites in cattle, there is considerable interest in obtaining FDA clearance. This drug, however, is not expected to be available for a few years.

Due to the potential disadvantages associated with the substitution of Comaphos, Prolate^R, and lindane economic impacts would be expected to cattlemen with scabies-infected cattle if toxaphene were cancelled. Economic impacts would include both increased scabies control costs and possibly increased cattle mortality (Comaphos and Prolate^R) or difficulties in application (lindane).

Since alternative pest control practices are expected to be as effective as toxaphene for most major pests, beef-cattle production levels would not be expected to be significantly impacted by a toxaphene cancellation. Although user impacts are expected for mite control, market level and consumer economic impacts would not be anticipated. These costs would be absorbed by the affected cattlemen.

More stringent storage and disposal requirements could increase the cost to cattlemen of toxaphene use. All new toxaphene labels (including amended labels) for livestock dip and spray use will require the pesticide applicator (including farmer operator applicators) to dispose of wastes according to Federal or approved State procedures under Subtitle C of the Resource Conservation and Recovery Act. See Chapter VI and the sample labels developed by the Agency. Compliance with this regulation will increase the costs of toxaphene applications.

D. Wheat

In 1980, approximately 80 million acres of wheat were planted and 71 million acres were harvested. The 1976 survey found that toxaphene was applied to 1.2 million acres in 12 states due to infestations of grasshoppers (93,000 acres), armyworms (336,000 acres), and army cutworms (765,000 acres) (U.S. Department of Agriculture 1977. 1976 Biological Survey For Toxaphene Assessment). Toxaphene applications were made at an approximate rate of 2.0 pounds (range 1.50-2.38 active ingredient) per acre applied once during the season (USDA/State Assessment Team on Toxaphene in cooperation with the Environmental Protection Agency. 1978). However, normally, toxaphene would not be used for army cutworm control.[28] More recent data (1979-1981) indicate that an average of 560,000 acres are treated annually with 1.1 million pounds toxaphene active ingredient primarily for grasshopper and armyworm control.

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[28] The use of toxaphene in 1976 for army cutworm control reflects an abnormal situation. 1976 was a year of extensive army cutworm infestations. In Oklahoma alone it is estimated that 2.5 million acres of wheat were treated with insecticides to control army cutworms. Toxaphene was probably applied in 1976 because all endrin supplies had been used due to the severity of the infestation.

Alternative insecticides are available to control grasshoppers and armyworms in wheat. The 1978 analysis identified alternative grasshopper controls as malathion, parathion, and phorate. Since the 1976 survey, carbaryl and carbofuran have also been registered for grasshopper control. Methyl parathion, trichlorfon, malathion, and parathion were identified in the 1978 analysis as toxaphene replacements for armyworm control. Since that time, methomyl has also been registered.

The economic impacts of a toxaphene cancellation for use on wheat include the changes in wheat yield (due to varying levels of efficacy of alternative insecticides) and changes in chemical control costs. Given the chemicals registered in 1976, the 1978 analysis indicated that if toxaphene were cancelled for grasshopper control, the combination of increased grasshopper control costs and reduced yields would result in revenue reductions ranging from $6.12 to $14.00 (1977 dollars) per acre. The variations of revenue reductions were primarily due to the variations in yield losses in different regions. The availability of carbaryl, dimethoate, and carbofuran could substantially reduce these impacts dependent on efficacy and costs of these chemicals compared to toxaphene.

The 1978 analysis indicated that if toxaphene were cancelled for armyworm control, the combination of increased armyworm control costs and reduced yields would result in an average net revenue reduction of $8.75 (1977 dollars) per acre. The regional revenue losses ranged from $0.66 to $20.01 (1977 dollars) per acre and were primarily dependent on the extent of yield losses. The registration of methomyl and carbaryl for armyworm control might reduce the impact of a toxaphene cancellation dependent on relative efficacy and chemical prices.

If yield losses were to occur with the cancellation of toxaphene's use on wheat, wheat production is estimated to decrease only slightly. Therefore, economic impacts at the market or consumer level would not be anticipated since these costs would be absorbed by the affected growers.

E. Soybeans (Insecticidal Application)

In 1980, approximately 68 million acres of soybeans were harvested in the United States. U.S. soybean production has increased substantially since the mid-1970's. In 1976, less than 50 million acres of soybeans were harvested. Of that number, the 1976 survey indicated that 488,000 acres were treated with toxaphene. More recent toxaphene usage data (1979-1981) indicate that nearly 1.6 million pounds toxaphene active ingredient are applied to 800,000 acres for insect control annually. The 1976 survey indicated that toxaphene was primarily applied for armyworm, bean leaf beetle, grasshopper, and green cloverworm control.

The 1978 analysis selected carbaryl and methyl parathion as the most likely substitutes for toxaphene. At that time both chemicals cost slightly more than toxaphene on a per treatment basis; however, the controls were considered as efficacious as toxaphene. Since the 1976 survey on which the 1978 analysis was based, chlorpyrifos and pydrin have been registered for insect control on soybeans. The registration of these new alternatives would tend to reduce the costs of a toxaphene cancellation.

Since yield losses are not anticipated if toxaphene is cancelled, user impacts are expected to be minimal. If impacts occur they would be limited to increased control costs. Since soybean production will not be affected there will not be any negative market and consumer impacts.

F. Sorghum

In 1980, 15.8 million acres of sorghum were planted for silage and grain. The 1976 survey indicated that during the 1976 growing season 304,000 acres were treated with 456,000 pounds of toxaphene (active ingredient) for control of armyworms, grasshoppers, and green cloverworms. Toxaphene applications were made once a year at the rate of 1.5 pounds active ingredient per acre. More recent data (1979-1981) indicate that an average of 110,000 acres are treated with 165,000 pounds toxaphene active ingredient annually.

The 1978 analysis assumed that if toxaphene were cancelled for use on sorghum, carbaryl and methyl parathion applications would be substituted. Annual treatment costs would increase from $3.22 per acre with toxaphene to $4.77 and $4.09 per acre for carbaryl and methyl parathion, respectively (1977 pesticide prices and dollars). Yield losses were not anticipated with the use of the two alternatives. Since 1976, additional insecticides have not been registered for application to sorghum for control of the above pests.

User impacts consisting of a change in control costs would be expected if toxaphene is cancelled. Due to the small percentage of sorghum acreage treated, and relatively low increase in treatment costs, economic impacts are not expected at the market or consumer level.

G. Soybeans (Herbicide)

In addition to toxaphene's insecticidal uses, toxaphene is also applied to soybeans as an herbicide for control of sicklepod (Cessia obtusifolia). Toxaphene has had EPA-State Special Local Need (SLN) Section 24c registrations in six southern states since 1980. Approximately 4.0 million pounds of toxaphene are applied to 1.0 million acres of soybeans annually for sicklepod control in the South.

Toxaphene is applied at 2.0 pounds active ingredient per acre in crop oil sprayed over top of soybeans when sicklepod is in the cotelydon stage. If necessary, an additional 2.0 pounds will be applied 14 days later with a maximum application of 4.0 pounds active ingredient per acre.

Linuron + 2,4-DB, and metribuzin are the major alternative sicklepod controls. Efficacy results suggest that toxaphene is a more reliable control of sicklepod in soybeans than available alternatives. Therefore, the use of alternatives results in yield and quality losses. If toxaphene's herbicidal use were cancelled growers currently using toxaphene would experience decreased soybean yields, increased combining costs, and a loss of value from a trash discount. In the aggregate, users would experience output reductions of 1.1-3.2 million bushels with farm income losses ranging from $8.8-$19.7 million annually (1981 dollars). The range is dependent on the ability of growers to adopt new cultural practices. On a per acre basis, toxaphene users would experience losses of $6.62-$43.84 per acre annually (1982 dollars). The range is dependent on the selection of alternatives (dependent on cultural practices) and weather conditions.

A toxaphene herbicide cancellation would result in soybean market impacts. Overall domestic soybean production would decrease. This would raise soybean prices $0.007 per bushel. This would increase the value of domestic soybean production approximately $14.2 million annually. Since a significant proportion of the U.S. soybeans are exported approximately $8.7 million would be added to the cost of soybeans consumed domestically. This $8.7 million dollar increase would most likely be passed on to consumers.

Over the next 5 years the user impacts will approach the lower end of the range. Southern soybean growers are adopting narrow row planting. Acceptance of this cultural practice results in the availability of additional sicklepod controls. As more alternatives to toxaphene become available, the economic impacts of a toxaphene cancellation would be reduced.

H. Peanuts (Insecticidal Application)

Approximately 1.5 million acres of peanuts are planted annually. The 1976 survey identified 94,000 acres treated with toxaphene for armyworm, leafhopper, thrip, and velvet bean caterpillar control. More recent toxaphene usage data (1979, 1981) indicate that currently approximately 80,000 acres are treated with 160,000 pounds toxaphene active ingredient annually.

The 1978 analysis identified carbaryl and methyl parathion as the most likely substitutes for toxaphene. At that time both chemicals cost slightly more than toxaphene on a per-treatment basis; however, the controls were considered as efficacious as toxaphene. Since 1976 carbofuran, chlorprifos, and fenvalerate have been registered for insect control on peanuts. The registration of these alternatives would tend to reduce the costs of a toxaphene cancellation.

Since peanut yield losses are not anticipated if toxaphene is cancelled, user impacts are expected to be minimal. Any impacts would be limited to increased control costs. Peanut production will not be affected; therefore, negative market or consumer impacts are not anticipated.

I. Peanuts (Herbicide)

Currently, Alabama is the only State with a toxaphene SLN registration for sicklepod weed control in peanuts. Use directions, application rates, equipment types, limitations and precautions contained on the label for peanuts are identical to those for soybeans. Reportedly, only a small percentage of Alabama peanut growers are using toxaphene for sicklepod control since adequate control is obtained from use of other herbicides commonly applied to peanuts. If toxaphene's Alabama herbicidal use were cancelled, economic impacts to Alabama peanut growers are expected to be minimal.

J. Minor Uses

As noted previously, toxaphene is registered for application to approximately 300 use sites. Although sufficient data were not available to individually assess the benefits for all 300 uses of toxaphene, the Agency in conjunction with the U.S. Department of Agriculture undertook a number of efforts to identify any minor uses which are critical to the agricultural economy. Of these 300 uses, only five specific use sites have been identified as having specific benefits which might outweigh any risks attendant to those uses. Moreover, these specific uses were identified as warranting attention because either there are no registered alternatives, or registered alternatives relative to toxaphene are considered to be less effective, less safe, or less available in local areas.

Sheep Dip

Toxaphene is one of the earliest "modern" pesticides for controlling ectoparasites of sheep. It is used by several states as a spray or dip to control such pests as scabies mites, sheep ked, lice, ticks, and fleeceworms (larvae of several species of flies which cause myiasis). In light of the vat management problems associated with the early use of the lindane wettable powder, toxaphene became a favored compound for use, particularly in dipping operations. Reportedly, if toxaphene were no longer available for use on sheep, it would be extremely difficult to control some pests because the remaining materials (coumaphos, lime sulfur, phosmet - approved by APHIS) are not as efficient.

No-Till/Limited Corn

Corn grown with no-till or limited tillage practices often encounter increased incidence of certain groups of pests. Rotations with small grains or sod seem to increase and amplify problems involving sod and soil insect pests such as white grubs, wireworms, and cutworms. One method of controlling these pests under limited tillage situations is to broadcast an insecticide over the entire field as opposed to over-the-row application or later foliar applications. Although there are a number of compounds registered for these pests, the 1982 USDA survey of the states and other agency efforts indicated that toxaphene is being used with increasing regularity in limited tillage corn farming. It appears that toxaphene is used in these situations primarily due to cost differential when compared to other registered pesticides; however, the Agency is unable to quantify the extent of this use practice due to a lack of data.

Armyworm, Cutworm, Grasshopper Control on Cotton, Corn, and Small Grains

A number of states emphasized a critical need for the use of toxaphene to control armyworms, cutworms, and grasshoppers on cotton, corn, and small grains [identified as oats, barley, wheat, rice and rye] in epidemic situations when alternative pesticides either are exhausted or ineffectual. These uses are considered critical because when sporadic infestations do occur, these pests are capable of rapidly destroying a crop. Although it is not possible to estimate the economic impact if toxaphene were not available for these uses, the impact on the agricultural economy would be expected to be significant due to the crisis nature of the need for toxaphene in these situations.

VI. IDENTIFICATION AND SELECTION OF REGULATORY ACTIONS

A. Introduction

Chapters III, IV and V examined the human and environmental risks associated with the uses of toxaphene, and identified the benefits associated with each major use. As described in Chapter I, FIFRA mandates that the Agency weigh the human and environmental risks against any economic benefits of the use(s) of a pesticide in order to determine whether uses can continue without unreasonable adverse effects. To carry out that mandate, there is a wide range of regulatory options available to the Agency. For each use pattern, the Agency evaluates each feasible regulatory option for its impact on both sides of the risk/benefit equation, and then selects the most appropriate course of regulatory action.

This Chapter describes the process by which the Agency developed potential regulatory options for toxaphene, provides a risk/benefit analysis for each of the options, and sets forth the regulatory measures which the Agency has decided are most appropriate to adopt and implement.

B. Legal Basis for Options

FIFRA provides the Administrator with three broad legal courses of action for a pesticide which is the subject of a rebuttable presumption against registration. These are:

1) Continue registration without additional restriction.

2) Continue registration, but amend the terms and conditions of registration.

3) Cancel registration.

Continued registration without restriction (Option 1) and cancellation (Option 3) are options which correspond to the opposite ends of the risk/benefit spectrum. Briefly, cancellation means that the sale and distribution of the pesticide at issue is prohibited; continued unrestricted registration means that sale and distribution are continued unchanged. Adoption of Option 1 is appropriate when the Agency concludes that the level of risk is reasonable in light of the pesticide's benefits and that further risk reduction measures are not necessary to assure that the use of the pesticide meets the statutory standard for continued registration.

Adoption of Option 3, cancellation, is appropriate when the Agency concludes that the risks from a use or uses outweigh the benefits of the use(s), and that these risks cannot be mitigated to a reasonable level, in light of the benefits, by any other measures short of cancellation. The effect of cancellation is to eliminate entirely both the risks of a pesticide's use or uses and the benefits of the use(s). Cancellation may affect all uses of a compound, or it may affect only specific uses, or specific formulations, or specific application methods. Cancellation may be conditioned on the completion of studies, or it may be delayed for a specified period of time to allow for development and implementation of satisfactory alternative pest control measures. Finally, the terms of cancellation may provide for the continued sale and use of existing stocks of the cancelled pesticide to such extent, under such conditions, and for such uses as would be consistent with FIFRA.

In the case of cancellation, the Administrator issues a notice of intent to cancel any or all registrations of pesticide products which are registered for the specified use(s) [FIFRA Section 6(b)(1)].[29/] Unless otherwise specified, such a cancellation notice becomes effective 30 days after receipt by the registrant or publication of the notice in the Federal Register, unless (1) the registration(s) are modified to the Agency's satisfaction or (2) a registrant or other adversely affected person requests a hearing on the cancellation of one or more registrations.

Between these polar alternatives of continued registration without restriction and cancellation exists a range of possible regulatory actions. In fact, FIFRA requires that

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[29/] Cancellations may also be the result of FIFRA section 6(b)(2) hearings. Because a 6(b)(2) hearing is not being proposed for toxaphene, it is not discussed in this document.

the Administrator shall "consider restricting a pesticide's use or uses as an alternative to cancellation..." [FIFRA Section 6(b)]. Although FIFRA does not specify what kinds of restrictions are to be examined, the Agency interprets this to mean amending the terms and conditions of registration in any fashion appropriate for the uses in question.

Adoption of this option is appropriate when the risks of a pesticide use can be reduced to a reasonable level, while preserving the benefits of the use, by modifying the terms and conditions of the pesticide's registration. These modifications, which are generally expressed through the pesticide's labeling, often include changes in the way the pesticide is used, the purposes for which it may be used, or where it may be used. Such changes in use are usually designed to reduce exposure of humans or animals to the pesticide, and thereby to reduce or even eliminate the risk from the pesticide.

C. Development of Regulatory Options

The development of regulatory options short of cancellation involves the formulation of modifications to the terms and conditions of registration which are intended to reduce the risks attendant to the use(s) of the pesticide. Each option is then evaluated to determine whether it achieves an adequate reduction in risk without causing unreasonable economic consequences, such that the remaining benefits of the use exceed the remaining risks of that use.

The process of developing a full range of regulatory options, with respect to pesticide products containing toxaphene, focused on ways to (1) minimize direct and indirect exposure to the general public, (2) reduce levels of exposure to nontarget organisms and endangered species, (3) reduce levels of exposure to toxaphene applicators, and (4) reduce exposure resulting from consumption of contaminated foods and water. By definition, such exposure reduction measures would result in comparable reductions in risk.

The Agency has assessed the various exposure situations at issue and has examined a number of specific measures by which exposure and risk might be reduced via amendments to the terms and conditions of registration. The risk reduction measures discussed in the following subsections have been assessed, taking into account potential effectiveness as well as economic and practical feasibility.

1. Restrictions Aimed at Reducing Occupational Risks of Toxaphene

The Agency examined the following measures designed primarily to reduce the risk of toxaphene exposure to applicators and other handlers of the pesticide.

a. Classify Toxaphene for Restricted Use Only and Require Applicator Certification

Under FIFRA, pesticides may be classified for restricted use and limited to use only by certified applicators. This measure would restrict toxaphene use to certified applicators and persons under their direct supervision. Certified applicators are required to complete a certification training program. Such programs, which are primarily administered by the states, are designed to encourage greater responsibility on the part of applicators and thereby reduce exposure and adverse effects.

b. Require Protective Clothing and Respirators or Use of Closed System Application

These modifications are intended to reduce risk by reducing dermal and inhalation exposure to toxaphene. The appropriate protective clothing to be worn to reduce toxaphene exposure consists of hats, impermeable gloves, rubber or synthetic rubber boots or boot covers, long-sleeved shirts, and long pants. This protective clothing would be required for all applicators and by all personnel involved in mixing, loading, transferring or otherwise handling this pesticide. Pilots of airplanes and helicopters could be exempt from this protective clothing requirement when flying aircraft, although the Agency would encourage the use of aircraft equipped with positive ventilation equipment. Pilots involved in the mixing-loading operation would be required to wear protective clothing and equipment during that operation.

Table IV-7 lists the estimated exposures to applicators when no protective clothing or respirators are worn. Use of appropriate protective clothing should reduce dermal exposure by approximately 80%; respirators should reduce respiratory exposure by approximately 90%. It should be noted that these estimates assume that the protective clothing and respirators will be in good repair and worn at all times that an exposure potential exists. The latter consideration is particularly important because of the extremely hot weather conditions found in the areas (primarily the Southeast) where cotton and much of the sorghum, soybeans, and peanuts to which toxaphene is applied are cultivated.

Recently, completely closed systems have been developed for the mixing, loading and application of pesticides. Ideally, proper use of an appropriate, working closed system should eliminate all exposure since applicators rarely come into direct contact with the pesticide during closed system applications. It is estimated that exposure (dermal and respiratory) for most applicators could potentially be reduced to insignificant levels through the use of these systems. Accordingly, requirements for protective clothing and respirators could be waived for most applicators when a closed system of application is used. However, because their activities are unaffected by the use of closed system application, flagger exposure and the need for protective measures would remain the same as with the more conventional application methods.

c. Prohibit Human Flaggers Unless Protected by a Totally Enclosed Vehicle

As determined by the Agency's exposure and risk analysis, human flaggers are the applicator group which is subject to the greatest exposure potential. This potential is significant even when adjustments for protective clothing and respirators are included in the exposure assessment.

Flaggers are individuals stationed at predetermined points in a field who indicate to pilots applying toxaphene where to begin (or stop) applying the pesticide. As a result, these individuals can come into direct contact with the pesticide and are at substantial risk as indicated in Table IV-8. This registration modification could further reduce occupational risk by requiring use of automatic flagging devices or fully protective enclosure of flaggers.

2. Modify Use Directions for Applying Toxaphene to Crops

The Agency has explored the possibility that risk and exposure to toxaphene could be reduced if use directions were modified to lower the frequency and timing of applications to crops during a single growing season. These modifications would have to be implemented while preserving effective results from the use. Included among the various use directions which could be implemented are specific limitations on reentry to areas where the pesticide has been applied, limitations on the dosage rates or methods, or requirement of a specific interval between application of the pesticide and harvest of crops in order to reduce the level of residues on foods.

3. Impose Consistent and Stringent Disposal Requirements for Toxaphene Used in Cattle and Sheep Treatment Operations

This risk reduction measure is designed to reduce contamination of the environment, particularly risk to fish from contamination of water bodies. Such environmental contamination results from the disposal of the treatment solution on land areas and from long storage of the treatment solution in storage facilities not appropriate for hazardous wastes. Disposal on land allows the material to be carried into streams via storm run-off, and long storage may permit excessive soaking into the soil or to ground water.

4. Establish or Re-evaluate Tolerances in Conjunction with FDA

Pursuant to Section 408 of the Food, Drug and Cosmetic Act the Administrator may establish tolerances for residues of a pesticide on raw agricultural commodities. Compliance with these tolerances is monitored and enforced by the Food and Drug Administration and the Department of Agriculture.

Most tolerances for toxaphene in foods were set pursuant to the "Spray Residue Hearing" and were based upon the analytical method for organic chlorine and the presumed toxicity of DDT. Toxaphene tolerances were first published in 1955 and are currently found in 40 CFR 180.138. Interim tolerances for toxaphene appear at 40 CFR 180.319. However, these toxaphene tolerances, for the most part, do not reflect measured residues of toxaphene in foodstuffs or state-of-the-art toxicological analyses regarding acceptable levels of toxaphene in food. Therefore, continued registration of toxaphene could necessitate re-evaluation of the current tolerances, and may require the development of additional data for some use patterns.

D. Selection of Regulatory Options

As noted earlier, the primary risks of concern with respect to toxaphene are those resulting from human and environmental exposure due to toxaphene distribution to air, water, soil, food sources and nontarget organisms. The benefits derived from the use of toxaphene, which can not be adequately met through the use of alternatives, are primarily associated with a limited number of uses. Based on its assessment of these risks and benefits, the Agency has determined that the registrations of products for most uses of toxaphene can be cancelled without placing an unreasonable burden on the agricultural community, and that application of products registered for the remaining uses can be continued, under certain conditions, without subjecting man and the environment to unreasonable risk.

1. Risk/Benefit Analysis of Options

An assessment of the regulatory options noted above clearly indicates that, although they may reduce exposure in some instances, alone they are not sufficient to reduce or eliminate the risks associated with the use of toxaphene to a reasonable level because, for the most part, they simply do not address several primary sources of exposure. For example, restriction of toxapnene use to certified applicators may reduce the potential for accidental occupational exposure to toxaphene, but would not significantly alter the occupational exposure resulting from proper use of the pesticide. Protective clothing and elimination of human flagger practices would directly benefit applicator and field worker populations, but would not affect the dietary exposure risks posed by toxaphene's use and would not reduce the risk to fish and avian populations, including endangered species. Moreover, even witn these protective measures, some serious applicator risks could remain.[30] In addition, the costs of these risk reduction measures may greatly outweigh any benefits associated with some of the marginal uses of toxaphene.

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[30] Factors such as equipment reliability and heat stress associated witn the use of protective clothing and respirators in the climatic conditions involved could significantly affect the success of such measures.

Regulatory options relating to use directions also would have little impact on overall exposure to toxaphene. While some reductions in risk would result to applicators and field workers, these measures do not address the environmental contamination problem, nor do they address the direct and indirect contamination of food and water. Regardless of use restrictions, toxaphene continues to persist in the environment long beyond the growing season, resulting in accumulations in soil and water. In addition, toxaphene is known to accumulate in the tissue of fish and game bird and mammalian species. Consequently, toxaphene residues in food and water sources result in human dietary exposure. Moreover, significant population reductions in nontarget organisms and endangered species could result from continued use of toxaphene regardless of particular use practices.[31]

The primary environmental concerns from toxaphene use stem from any entry of the chemical into the environment, regardless of the application method or care taken in handling and use. Toxaphene is extremely persistent and may be transported from the agricultural use sites by run-off and other environmental mechanims). Therefore, application in one area could result in residues in other untreated or treated areas. The cumulative effects of past loading of toxaphene in the environment may be seen in the widespread detection of residues in environmental media. Accordingly, local risk reduction measures are not adequate to alter this pattern because it is not possible to isolate toxaphene exposure to areas of use.

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[31] Field kills of birds have been observed even following toxaphene application at and below the lowest recommended application rates.

In light of these factors, it is clear that the risks resulting from toxaphene use are as much a function of total amount used, as proximity to use areas. Accordingly, it is futile to restrict uses of toxaphene as a risk reduction measure, unless the use restrictions are accompanied by a great and dramatic reduction in total volume of toxaphene used. The prudent course of action is to limit the use of toxaphene to only those uses where the benefits clearly outweigh the risks. In making this determination, the Agency considered implementation of various use restrictions to reduce the risks to the lowest feasible levels.

Based on its analysis, the Agency has determined that cancellation of most toxaphene registrations is the only appropriate course to avoid unreasonable adverse effects upon the environment. Relative to all of the major registered uses of toxaphene, except for scabies treatment of beef cattle and sheep, the benefits have not been demonstrated to exceed the risks, even when risk reduction measures are considered. A number of efforts have been made to identify any minor uses which have specific benefits which might outweigh the risks attendant to that use.[32] As a result of these efforts, the Agency has developed exceptions to cancellation for certain minor uses (and the conditions for use of existing stocks) based in part upon information relating to the economic value of specific uses of toxaphene. Finally, the Agency has concluded that it is environmentally more prudent to allow the use of existing stocks of toxaphene under very limited and well-controlled conditions, over a finite period of time, than to possibly overload the environment and/or waste facilities by ordering immediate disposal.

Relative to the remaining uses of toxaphene, the Agency has determined that certain conditions should be imposed in order to reduce occupational exposure to the lowest level feasible. Based on the Agency's analysis, certain categories of applicators may be at substantial risk because of their exposure to toxapnene. Use of protective clothing and other risk reduction measures can reduce applicator exposure substantially. In addition, applicator certification, which is designed to foster greater responsibility and application expertise, would also enhance the reduction of occupational exposures. Moreover, better trained applicators should be better able to minimize environmental contamination during application. For the retained uses of toxaphene, the cost to users resulting from the implementation of these restrictions is justified by the reduction in occupational risks which would accrue from their imposition.

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[32] USDA was requested on two occasions to identify such uses and the RPAR process permitted public input on this issue.

Among the major uses of toxaphene, there was particular concern regarding the cancellation of toxaphene use for scabies treatment of beef cattle and sheep in vat dips and spray-dip machines because of the general unavailability of cost-effective alternatives, and the danger to cattle and sheep if no treatment were used (see Chapter V). Although the agency is aware that certain problems are associated with these uses, e.g., exposure and contamination from runoff and uncontrolled disposal, it also recognizes that these uses of toxaphene are of great significance to the beef cattle and sheep industry. Accordingly, the Agency has carefully examined these use patterns to determine if an adequate balance can be reached between the risks and benefits through some mechanism short of cancellation.

As noted earlier in this document, on the one hand, toxaphene use can result in risks to avian, aquatic and mammalian species, including man, through direct application, aerial transport, and runoff from cattle and sheep holding areas.

Uncontrolled disposal of solutions used in scabies treatment of cattle and sheep also is another potential source of contamination. On the other hand, however, toxaphene is considered to be the most efficacious and cost-effective treatment of cattle and sheep for scabies control. Agency records show that no efficacious new pesticides have been registered for scabies control since 1976, and developments in this area are progressing slowly. While lindane was recently approved by APHIS for scabies treatment, it is not considered as efficacious as toxaphene because of difficulties in maintaining a proper concentration in the dipping vats. Moreover, lindane is reported to be more abrasive to equipment than toxaphene. Ivermectin, the new animal health compound under study by FDA, is not expected to become marketable for a number of years.

Of the 16.9 million beef cattle treated with toxaphene in 1976, Agency records indicate that less than 900,000, or 5 percent, were treated for scabies control. Although no number is available for use on sheep, it is estimated that the number is considerably less than that for cattle.

In assessing the risks and benefits noted above, the Agency concludes that the benefits of toxaphene use for scabies control clearly outweigh the risks. Accordingly, the Agency proposes to continue the registrations of toxaphene products for scabies treatment of beef cattle and sheep. Because of problems associated with this use, the Agency will monitor the development of alternatives on an ongoing basis.

In continuing registrations of toxaphene for scabies treatment, only the vat dip and spray-dip machine methods of treatment are being allowed, based on the predictions that these methods of application result in less applicator exposure than the spray method of treatment, and that environmental contamination can be more easily controlled than in spray application. Continued registration is being permitted subject to certain modifications in the terms and conditions of use.

The registrations of products for a limited number of minor uses of toxaphene are being continued, subject to very rigid restrictions. These minor use registrations relate to the use of toxaphene for the control of armyworms, cutworms and grasshoppers on cotton, corn and small grains in epidemic situations when alternative pesticides are either exhausted or ineffectual. Because of the emergency conditions required before toxaphene can be used in these instances, it is likely that these uses will not add a significant increment to the total annual environmental load of toxaphene. Moreover, even in these emergency situations, use restrictions are being imposed to reduce human and environment contamination. In addition to the above minor uses for epidemic conditions, the Agency is also continuing the use of toxaphene to control mealybugs and pineapple gummosis moths on pineapples and weevils in bananas in the Virgin Islands and Puerto Rico.

Finally, the Agency has determined that existing stocks of toxaphene may be used, under very restricted conditions, for specified periods of time without unreasonable adverse effects on man and the environment, and in a manner which minimizes the impacts of cancellation on the agricultural economy. An important consideration in any cancellation decision is the proper disposal of existing stocks. In this instance, if no provisions were made for the use of these products, all of the stocks would require costly disposal as hazardous waste. Choice of this option would consume valuable, limited space in the designated disposal facilities. Moreover, because of the extra cost and inconvenience of hazardous waste disposal, the potential for improper disposal of the stocks, and the resultant environmental hazard, cannot be ignored. Therefore, well-reasoned provisions for use of existing stocks are consistent with integrated environmental policy-making. In order to permit continued use of the existing stocks of toxaphene in a manner consistent with FIFRA, the Agency will impose conditions which will substantially reduce the human and environmental exposure associated with the period of time during which the stocks are to be used. These conditions severely limit the use, application and disposal of toxaphene, in addition to prescribing specific protective measures for applicators. However, mindful of FIFRA's mandate regarding impacts on the agricultural economy, the Agency has determined that, to the extent environmentally feasible, use of the existing stocks will be directed to the most economically beneficial uses of toxaphene. Choice of this approach by the Agency will allow for the orderly transition from toxaphene to efficacious alternatives over the next few years, without unreasonable adverse effects on man or the environment, and with a minimum economic impact on the agricultural community.

Accordingly, the Agency has determined that the existing stocks of toxaphene may be used as a herbicide on soybeans and peanuts to control sicklepod. These uses have become high volume uses of toxaphene because the benefits to the agricultural economy are noticeably greater than for any of the insecticidal uses of toxaphene. Use of existing stocks will also be permitted for no-till corn cultivation, dry peas and southern peas because of the value to that segment of the agricultural economy. Use of existing stocks on other sites and for other pests may also be allowed during the period of permitted use of existing stocks where an appropriate showing of need is made, or for the minor use patterns as described above. Additional conditions for the use of existing stocks related to supplemental labeling are also imposed.

Stocks which consist of formulations which cannot be made suitable for the uses identified above may be labeled for use on the pests and sites contained on present labeling for such stocks and may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received to be held for delivery by any person only until December 31, 1983.

The Agency has determined that the provision to permit use of existing stocks should be designed in a manner that provides for the minimum total loading of toxaphene into the environment which is sufficient to permit use of the stocks. Accordingly, during the period designated for exhaustion of existing stocks (i.e., until December 31, 1986), no registrant may produce or import technical toxaphene except as provided herein. Beginning thirty days from receipt by the registrant of the decision published in the Federal Register, all formulations of toxaphene for registered uses must be made from material designated as existing stocks under the terms and conditions of the decision. This requirement shall be in effect until (1) December 31, 1986 or (2) such time as the Agency finds that any registrant has made a showing that existing stocks are no longer available from which to formulate products for the registered uses, whichever is earlier.

2. Regulatory Decision

Based on the discussion above, the Agency has determined that the following regulatory procedures will protect man and the environment from unreasonable adverse effects from the continued use of toxaphene, while allowing the agricultural community access to toxaphene for certain critical uses. To the extent that continued registration or use is allowed, those uses or registrations will be continued and future applications for registration granted only if the registrants or applicants incorporate the following terms and conditions in the registrations and labeling of all toxaphene products:

a. All Uses

Except as provided below, all registrations for pesticide products containing toxaphene are cancelled, effective as of the end of the statutorily prescribed 30-day period.

b. Manufacturing Use Products

Registrations of products for use solely as manufacturing use products or technicals must be amended in accordance with the following requirement:

Labels must state that the product is for use only to formulate pesticide products which are registered in accordance with the Notice of Intent to Cancel or Restrict Registration of Pesticide Products Containing Toxaphene.

c. Scabies Control on Beef Cattle and Sheep

(1) Toxaphene products may be registered for use to control scabies on beef cattle and sheep, subject to terms and conditions noted below.

(2) To avoid immediate cancellation, registrants who wish to retain the beef cattle and sheep dip use for their products must request that their registrations be amended by revising the products' labels to provide that:

(a) The product may be used only to treat scabies on beef cattle or sheep;

(b) Application may be made only by dipping exposed or infected beef cattle or sheep in toxaphene vat solutions, or by using a spray-dip machine;

(c) The products are classified as Restricted Use pesticides (for use only by certified applicators);

(d) Label directions relating to vat cleaning and mixing are included to assure that the handling of materials and maintenance of percentage of toxaphene in the mix protect applicators. Prohibitions against disposal or dispersal to ponds, lakes, streams and other water bodies must also be included.

(e) Applicators must wear boots, extended impermeable gloves, head covering, aprons, long pants, long-sleeved shirts, and respirators.

(f) Used dip solutions must be disposed of in accordance with the Resource Conservation and Recovery Act (RCRA). If the owner generates more than 1000 kg of used dip solution per month or more than 1000 kg of used dip solution in combination with other hazardous waste, the material must be treated as hazardous waste subject to subpart C of RCRA. Any user who wishes to manage hazardous waste must obtain a permit to serve as a hazardous waste facility pursuant to RCRA. The label may exempt from these disposal requirements any farmer/rancher who uses the product solely to treat beef cattle or sheep which he and/or his immediate family owns as individuals.

(g) Manufacturing and/or formulation of products for this registered use must be in accordance with item g. below.

d. Minor Uses: Armyworm/Cutworm/Grasshopper Control

(1) Toxaphene products may be registered for use to control sporadic infestations of armyworms, cutworms or grasshoppers on cotton, corn, and small grains, subject to the terms and conditions noted below To avoid immediate cancellation, registrants who wish to retain this use for their products must amend their registrations to provide for the following label requirements:

(a) The amended labeling must be restricted solely to treatment of armyworms, cutworms, or grasshoppers on cotton, corn, or small grains.

(b) All sale, offers for sale, holding for sale, distribution, shipment, delivery for shipment, receipt for shipment, offers for delivery, and use are restricted to emergency situations. Accordingly, all labels must provide that sale, distribution or use is permitted only after a showing of emergency conditions to EPA by a federal or state agency and issuance by EPA of a finding that an emergency condition exists. The showing must be particularized regarding the extent of the infestation and proposed treatment (e.g., acreage involved, poundage of toxaphene needed, period during which treatment is permitted, application methods), and any finding that emergency conditions exist may impose restrictions relating to, among other things, geography, crop site, poundage, or duration. Agencies and states may of course anticipate conditions which would constitute an emergency and obtain approval in advance to use the product if the state or federal agency shows that conditions prevail which are precursor to emergency conditions.

(c) Toxaphene products registered for use to control armyworms, cutworms or grasshoppers on cotton, corn, and small grains must bear a Restricted Use classification (for use only by certified applicators).

(d) For aerial applications, flagging must be by fully automated mechanical means or by humans working in totally enclosed vehicles.

(e) Protective clothing and respirators must be required for all applicators and other personnel involved in mixing, loading, transferring or otherwise handling this pesticide. Protective clothing must consist of hats, impermeable gloves, rubber or synthetic rubber boots or boot covers, long-sleeved shirts and long pants. Full-face respirators are recommended; half-face respirators are required.

In lieu of compliance with the protective measures required for applicators, users may use closed system methods of mixing, loading and handling. However, it is recommended that mixers and loaders wear water proof gloves. Aerial applicators in positive pressure cockpits and other applicators in comparable ground equipment with appropriate filters at all air intakes need not comply with these protective clothing requirements.

(f) Labels (Environmental Hazard section) must contain the following statement:

> "This product is toxic to fish, birds and other wildlife. Use of this product may be fatal to birds and other wildlife in treated areas. Do not spray over lakes, streams, ponds, tidal marshes and estuaries. Do not apply where runoff is likely to occur. Do not apply when weather conditions favor drift from areas treated. Do not contaminate water by cleansing of equipment, or disposal of wastes. Overspray of this product into water at application rates recommended on

this label may be fatal to shrimp and crab; do not apply where these are important resources. Apply this product only as specified on this label."

(g) Manufacturing and/or formulation of products for this registered use must be in accordance with item g. below.

e. Minor Uses: Mealybug and Pineapple Gummosis Moth Control on Pineapples and Weevils in Bananas

Toxaphene products may be registered for use to control mealybugs and pineapple gummosis moth on pineapples and weevils in bananas, subject to terms and conditions noted below. To avoid immediate cancellation, registrants who wish to retain this use for their product must amend their registrations to provide for the following label requirements:

(1) The use must be restricted solely to treatment of mealybugs and pineapple gummosis moths on pineapples and weevils in bananas.

(2) The labeling must state "For Use Only in Puerto Rico and the Virgin Islands."

(3) The labeling must state that the product bear a Restricted Use classification (for use only by certified applicators).

(4) For aerial applications (if any), flagging must be by fully automated mechanical means or by humans working in totally enclosed vehicles.

(5) Protective clothing and respirators must be required for all applicators and other personnel involved in mixing, loading, transferring or otherwise handling this pesticide. Protective clothing must consist of hats, impermeable gloves, rubber or synthetic rubber boots or boot covers, long-sleeved shirts and long pants. Full-face respirators are recommended; half-face respirators are required.

(6) Manufacturing and/or formulation of products for this registered use must be in accordance with item g. below.

f. Existing Stocks Provision

Pursuant to Section 6 of FIFRA, the following provisions relate to existing stocks of cancelled toxaphene products existing within the territorial United States on or before the date of publication of the decision in the Federal Register.

(1) Existing stocks are defined as any toxaphene formulated for end use, any technical toxaphene, and any materials obtained and possessed by a registrant for use in manufacturing toxaphene which cannot be diverted for any other use by the registrant or for sale on the open market for any purposes other than manufacture of toxaphene.

(2) Within thirty days from the date of receipt of the Notice, any registrant holding existing stocks of toxaphene, as defined in subsection 1 above, may provide the Agency with a request to qualify for the provisions for existing stocks provided by the Notice, and shall provide the Agency with an itemized inventory of its stocks. Failure to submit such a request will result in a requirement that any cancelled stocks possessed by a non-requesting registrant be disposed of within 90 days of publication of the Notice. Such disposal must be in the manner required by the Resource Conservation and Recovery Act. Each registrant who qualifies for the existing stock provision shall submit on each annual anniversary of the Notice, an update of the inventory, including depletion of the inventory, sufficiently detailed to allow the Agency to follow dispersal of the original inventory.

(3) Existing stocks may be applied only on the sites described in subsection (4)(a) below (in addition to the retained registered uses).

(4) Except as provided in item (7) below, these stocks may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered for delivery to any person until the time periods specified in subparagraph (4)(a) below, only when accompanied by supplemental labeling which contains the following limitations and conditions:

(a) Stocks which consist of or can be made into formulations suitable to the uses designated in this paragraph must be labeled for use only to control sicklepod on soybeans and peanuts in those states which presently have 24(c) registrations or in any other state which, during this period, makes a special local need finding; for use to control insects in corn cultivated without tillage and in dry and southern peas; for emergency use pursuant to subsection (5) below only until December 31, 1986. Stocks which consist of formulations which cannot be made suitable for the uses listed above, may be applied in accordance with the use patterns contained on present labeling for such stocks and may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received to be held for delivery by any person only until December 31, 1983.

(b) For aerial applications, flagging must be by fully automated mechanical means or by humans working in totally enclosed vehicles.

(c) Protective clothing and respirators must be required for all applicators and other personnel involved in mixing, loading, transferring or otherwise handling this pesticide. Protective clothing must consist of hats, impermeable gloves, rubber or synthetic rubber boots or boot covers, long-sleeved shirts and long pants. Full-face respirators are recommended; half-face respirators are required.

In lieu of compliance with the protective measures required for applicators, users may use closed system methods of mixing, loading and handling. However, it is recommended that mixers and loaders wear water proof gloves. Aerial applicators in positive pressure cockpits and other applicators in comparable ground equipment with appropriate filters at all air intakes need not comply with these protective clothing requirements.

(d) Labels (Environmental Hazard section) must contain the following statement:

> "This product is toxic to fish, birds and other wildlife. Use of this product may be fatal to birds and other wildlife in treated areas. Do not spray over lakes, streams, ponds, tidal marshes and estuaries. Do not apply where runoff is likely to occur. Do not apply when weather conditions favor drift from areas treated. Do not contaminate water by cleansing of equipment, or disposal of wastes. Overspray of this product into water at application rates recommended on this label may be fatal to shrimp and crab; do not apply where these are important resources. Apply this product only as specified on this label."

(5) Additional uses may be permitted of existing stocks until December 31, 1986 with appropriate supplemental labeling upon a showing by any federal or state agency that

emergency conditions exist and a finding by EPA that the emergency conditions warrant use of these existing stocks for the requested purpose.

(6) The supplemental labeling required by subsection 4 above may accompany present labeling of the product appropriately identified as a cancelled product permitted for distribution, sale, offers for sale, holding for sale, shipment, delivery for shipment, receipt to deliver, or use only until December 31, 1986. Alternatively, registrants may modify present labeling to incorporate the supplemental labeling so long as the modified labeling is accepted by the Agency to contain all necessary provisions from the labels of the cancelled products and properly identifies the products as permitted for sale, distribution, and use only until December 31, 1986.

(7) Existing stocks not within the physical possession of any registrant (e.g., possessed by dealers and retailers) may be sold, shipped, or distributed for use in accordance with the labeling presently accompanying the product until December 31, 1983. Stocks within the physical possession of a registrant include, but are not limited to, stocks stored in facilities owned or leased by the registrant. Existing stocks in the hands of users on or before December 31, 1983 may be used in accordance with the labeling accompanying the product in the hands of the users.

(8) Pursuant to the authority of FIFRA Section 6(a)(1), existing stocks of any toxaphene product whose registration is cancelled pursuant to this Notice may not be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, received for delivery, or offered for delivery by or to any person or used by any person in any State in any manner which would violate FIFRA Section 12 if the product were still registered. Except as provided in item (7) above, such products shall be made available for use only by, and used only by, certified applicators or persons under the direct supervision of a certified applicator, and the supplemental labeling shall so state. For purposes of this paragraph, and FIFRA Sections 12(a)(1)(B) and (C), the term "statement required in connection with [the product's] registration" shall mean the statement on file with the Administrator in connection with the product's registration on the effective date of cancellation of the product, as modified by labeling changes required by this Notice, or by other modifications approved by the Administrator.

(9) After December 31, 1986, existing stocks may not be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, received to deliver or used for pesticidal purposes, and any stocks of products which are unused after that date must be disposed of in the manner prescribed by the label or as required by the Resource Conservation and Recovery Act.

g. Limitation on Toxaphene Sources

The Agency has determined that the provision to permit use of existing stocks should be designed in a manner that provides for the minimum total loading of toxaphene into the environment which is sufficient to permit use of the stocks. Accordingly, beginning thirty days from receipt by the registrant of the decision published in the Federal Register, all formulations of toxaphene for registered uses must be made from material designated as existing stocks under the terms and conditions of the decision. (2) This requirement shall be in effect until (a) December 31, 1986 or (b) such time as the Agency finds that any registrant has made a showing that existing stocks are no longer available from which to formulate products for the registered uses, whichever is earlier.

E. Conclusion

The Agency has determined that the use of toxaphene, as currently registered, causes unreasonable adverse effects to man and the environment. Based on its analysis of the risks and benefits of toxaphene use, the Agency has further determined that immediate cancellation of most toxaphene registrations is the appropriate course to reduce risks to a reasonable level. However, because of the importance of some uses to the agricultural community the Agency has decided to retain registrations for certain minor uses and to allow limited use of existing stocks. The Agency has imposed strict limitations on the continuing uses of toxaphene, such that the overall effect of this limited continued use of toxaphene is that it will not result in unreasonable adverse effects to man and the environment.

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[OPP-30000/13A; PH-FRL 2233-8]

Toxaphene; Intent To Cancel or Restrict Registrations of Pesticide Products Containing Toxaphene; Denial of Applications for Registration of Pesticide Products Containing Toxaphene; Determination Concluding the Rebuttable Presumption Against Registration; Availability of Decision Document

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Intent to Cancel or Restrict Registrations and Notice of Denial of Applications for Registration.

SUMMARY: Toxaphene-containing products are registered as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 USC 136 et. seq. In May, 1977, EPA initiated a process to consider whether the registrations for toxaphene products should be cancelled or modified. This Notice concludes that process and announces the Administrator's intent to cancel the registrations of toxaphene for most uses and to deny applications for registration of toxaphene not in accordance with the terms of this Notice. Registrations of products for scabies treatment of beef cattle and sheep in vat dips and spray-dip machies are continued, although amendment of the terms and conditions of registration for this use will be required. EPA has also decided to continue registrations of products for certain minor uses to control sporadic infestations of armyworms, cutworms and grasshoppers on cotton, corn and small grains, if the terms and conditions of registration are amended to provide, among other things, that toxaphene products may be sold, distributed and applied to these use patterns only if a prior finding of specific emergency need for toxaphene has been made by EPA. Finally, continued registration of toxaphene will also be permitted for use only in the Virgin Islands and Puerto Rico to control mealbugs and pineapple gummosis moths on pineapples and weevils in bananas. Stocks of toxaphene existing within the territorial United States as of the date of publication of this Notice in the **Federal Register** may be used under certain restricted terms and conditions until the time periods specified in Unite III F. below.

DATE: Requests for a hearing must be received on or before December 29, 1982, or (for registrants) within thirty (30) days from receipt of this Notice, whichever occurs later.

ADDRESSES: Requests for a hearing must be submitted to: Hearing Clerk (A-110), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460.

Copies of the Decision Document are available upon request from: Juanita Wills, Special Pesticide Review Division (TS-791), Office of Pesticide Programs, Environmental Protection Agency, Room 711, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

FOR ADDITIONAL INFORMATION CONTACT: Juanita Wills (703-557-7420).

SUPPLEMENTARY INFORMATION: On October 18, 1982, EPA publicly announced its decision to terminate the RPAR for toxaphene. The Notice published here and a companion mailing to registrants constitute the Agency's formal determination with respect to toxaphene and actions resulting from implementation of that determination. This Notice differs slightly from an advance copy informally distributed at the press conference held on October 18, 1982. The distributed Notice has been modified to reflect certain changes to the provisions governing existing stocks of toxaphene, set forth at Unit III F. of this Notice. Following the informal dissemination of the Notice signed on October 15, 1982, it became clear that the provisions for existing stocks would result in an unintended requirement that a significant portion of the stocks be disposed as hazardous waste because they could not qualify for the authorization for use provided in the Notice.

In this official Notice, limited provisions have been included to address stocks which have moved into commerce beyond the physical control of registrants, certain stocks which are formulated in a manner which does not permit them to be utilized on the crop sites designated for the longer term existing stocks provisions, and disposal of hazardous waste. Accordingly, all persons should take notice that the legally effective terms of this decision are those set forth in this published Notice.

I. Introduction

A. Regulatory Framework

Before a pesticide product may be sold, held for sale, or distributed in either intrastate or interstate commerce, the product must be registered [FIFRA sections 3(a) and 12(a)(1)]. A pesticide product will be registered only if it performs its intended pesticidal function without causing "unreasonable adverse effects on the environment" [FIFRA section 3(c)(5)], that is, without causing "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of [the] pesticide" [FIFRA section 2(bb)]. (A registration is a license allowing a pesticide product to be sold and distributed for specified uses in accordance with specified use instructions, precautions, and other terms and conditions.) For a pesticide product to be registrable, the benefits of each of its uses must exceed the risks of that use when the product is used in accordance with commonly recognized practice and in compliance with the terms and conditions of registration. The burden of proving that a pesticide product satisfies the criteria for registration is on the proponents of initial or continued registration.

Under FIFRA section 6, the Administrator may cancel the registration of a pesticide product or modify the terms and conditions of its registration whenever it is determined that the pesticide product causes unreasonable adverse effects on the environment. The Agency created the Rebuttable Presumption Against Registration (RPAR) process to facilitate the identification of pesticide products (or uses thereof) which may not satisfy the statutory standard for registration, and to provide an informal procedure through which to gather and evaluate information about the risks and benefits of these products and uses. The regulations governing the RPAR process are set forth at 40 CFR 162.11.

A rebuttable presumption arises if a pesticide meets or exceeds any of the risk criteria set out in the regulations. The Agency announces an RPAR by publishing a notice in the **Federal Register** and by issuing a Position Document (PD 1), detailing the Agency's position and concerns. Registrants and other interested persons are invited to review the data upon which the presumption is based and to submit data and information to rebut the presumption of risk by showing that the Agency's initial determination of risk was in error, or by showing that use of the pesticide is not likely to result in any significant exposure to human beings or the environment. In addition to submitting evidence to rebut the risk presumption, respondents may submit evidence concerning the economic, social and environmental benefits of the use of the pesticide.

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The RPAR process is concluded with a notice in which the Agency states and explains its decision as to whether the presumption of risk has been rebutted. If all presumptions of risk are successfully rebutted, the RPAR is concluded and no regulatory action is commenced. If the Agency determines that any presumption of risk is not rebutted, the notice of determination contains an evaluation of the information available to the Agency concerning the social, economic, and environmental costs and benefits of continued use of the pesticide for each individual use pattern. In determining whether each use of such a pesticide poses risks which are greater than the benefits, the Agency considers possible changes to the terms and conditions of registration which can reduce risk, and the impacts of such modifications on the benefits of the use. The final notice of determination is typically supported by a Decision Document (or final Position Document).

The final notice of determination may include a notice of intent to cancel the registrations of currently registered pesticide products or to deny applications for the registration of new products. It may also set out conditions which, if fulfilled by the registrant, would be adequate to bring the registrations into compliance with the statutory requirements and thus avoid cancellation or denial of registration, such as the removal of some uses from the label or changes in methods of application. The final notice may also require that the registration of the pesticide be reclassified from general to restricted use pursuant to FIFRA section 3(d)(2). For pesticides whose registrations are cancelled, the final notice may permit the continued sale and use of existing stocks under such conditions and for such uses as may be specified, if such sale and use would not be inconsistent with FIFRA and would not have unreasonable adverse effects on the environment. Prior to the issuance of a final notice of intent to cancel, FIFRA sections 6(b) and 25(d) require the Agency to submit notices proposed pursuant to section 6 to the Secretary of Agriculture and a Scientific Advisory Panel for comment. Any person adversely affected by a Notice of Intent to Cancel or a Notice of Denial may request an administrative hearing to challenge the proposed action, pursuant to FIFRA section 6 (b) and (d).

B. Background

In the Federal Register of May 25, 1977 (42 FR 26860), EPA issued a Notice of Rebuttable Presumption Against Registration and Continued Registration of Pesticide Products Containing Toxaphene. The Agency based the presumption against registration primarily upon studies showing that toxaphene causes tumors in laboratory animals; evidence demonstrating the acute toxicity of toxaphene to acquatic organisms; and the high likelihood that toxaphene causes reductions in the populations of nontarget animal species. The Agency also identified evidence of other toxic effects of toxaphene and hazard to endangered species. The Agency invited rebuttal or other comment on these risks and the other issues raised by the presumption against toxaphene registration.

Since publishing the RPAR, the Agency has evaluated the comments received from registrants and others regarding the risks and benefits of toxaphene. The Agency has reassessed toxaphene's chemistry, environmental activity and movement, toxicity, effects upon wildlife populations, and the exposure of humans and animals to toxaphene, and has evaluated the benefits of toxaphene use and the effects of cancellation upon the agricultural economy.

These evaluations and analyses confirm that toxaphene induces cancer in laboratory animals and is acutely and chronically toxic to aquatic life and birds (including endangered species). Examination of the patterns of use and the potential for exposure indicates that toxaphene is extremely persistent, moves readily through the environment, and contaminates habitats of vulnerable aquatic and avian species at levels sufficient to reduce their populations, and that humans are exposed to toxaphene through occupational contact and contamination of a range of food products, particularly fish. The potential risks to wildlife and human health resulting from toxaphene exposure were found to be extremely high. By contrast, the economic and agricultural benefits associated with most major uses of toxaphene are found to be slight, given the availability of efficacious alternatives for most uses.

C. Content of This Notice

This Notice announces the Agency's intent to cancel the registrations of toxaphene-containing products for most pesticide uses and provides notice of the availability of the Decision Document concluding the RPAR for toxaphene. The Agency has determined that for most uses of toxaphene remedial measures short of cancellation would not suffice to avoid unreasonable adverse effects on the environment because the primary risks from toxaphene usage result from dispersion into the environment which will occur regardless of any restrictions on application practices. Therefore, the Agency has determined that the registrations for most uses should be cancelled. Certain minor uses of toxaphene may be retained, but only if measures are taken to assure that the risks of continuing these uses do not exceed the benefits. Finally, the Agency has determined that the existing stocks of cancelled products may be use for a specified period, subject to strict requirements, in part because such use is judged to be the most desirable means of achieving disposal of those stocks.

The Toxaphene Decision Document summarizes earlier actions taken by the Agency concerning toxaphene, and sets forth the Agency's rationale for the cancellation of toxaphene registrations and other elements of the regulatory decision. A summary of the Agency's final regulatory decision on toxaphene is presented in Table 1 of this Notice; details of the decision are set forth in Unit III of this Notice.

TABLE 1.—SUMMARY OF FINAL REGULATORY DECISION ON TOXAPHENE

Use site	Final decision
All uses, except as described below Scabies control on beef cattle and sheep-vat dip and spray-dip machine methods only.	Cancellation, effective thirty days after receipt of this Notice. Continued registration Restrict use to certified applicators; require respirators and protective clothing for applicators; improved use and disposal requirements to reduce human and environmental exposure.
Minor Uses: Armyworm cutworm, and grasshopper control on cotton, corn and small grains.	Continued registration for use in demonstrated emergency situation. Restrict use to certified applicators; require respirators and protective clothing for applicators; improved directions to reduce exposure.
Mealybug and pineapple gummosis moth control on pineapples and weevil control in bananas in the Virgin Islands and Puerto Rico only.	Continued registration for use in Virgin Islands and Puerto Rico only. Restrict use to certified applicators; require respirators and protective clothing for applicators; improved directions to reduce exposure.

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TABLE 1.—SUMMARY OF FINAL REGULATORY DECISION ON TOXAPHENE—Continued

Use site	Final decision
Existing stocks of cancelled toxaphene product	Sale and distribution of existing stocks allowed for specified time periods, subject to strict requirements. For suitable formulations, sale and distribution for use to control sicklepod in soybeans and peanuts, use on no-till corn, dry peas, southern peas, and emergency use situations are allowed until December 31, 1986. For other formulations (unsuitable for conversion to the above uses) sale and distribution for use on presently registered sites are allowed until December 31, 1983.

Unit V of this Notice sets out the procedures by which a registrant or other person adversely affected by this Notice may request a hearing to challenge the actions proposed in this Notice. Unit V also sets out the procedures which registrants should follow in seeking amendments of their registrations to conform with the requirements of this Notice in order to continue their registrations for those uses of toxaphene products which may be retained under this Notice.

II. Summary of Risks and Benefits of the Pesticidal Use of Toxaphene

In reaching the decisions set out in the Toxaphene Decision Document, the Agency has considered information on potential health risks, environmental effects and the economic and social benefits associated with the pesticidal uses of toxaphene. The detailed assessments of risks and benefits and the conclusions regarding its use are set forth in the Toxaphene Decision Document. This section of the Notice summarizes those discussions.

A. Determination of Risks

Based on studies in laboratory animals, monitoring data, and ecological reports, the Agency has concluded that the use of toxaphene as a pesticide poses risks of: (1) Chronic effects to wildlife with potential applicability to humans (e.g., effects on growth and on collagen content in backbones of exposed fish and birds); (2) acute toxicity to aquatic organisms; (3) population reduction in non-target organisms; and (4) increased potential for oncogenicity to humans. Much of the information supporting this conclusion was set forth in the Toxaphene Position Document 1. As developed fully in Appendix A to the Decision, the Agency has determined that the information submitted to refute the risk concerns cited above was insufficient to overcome the presumption against toxaphene for these effects. Moreover, additional information has become available to the Agency since the issuance of the RPAR which substantially reinforces the Agency's conclusion.

Exposure to toxaphene poses a substantial risk to certain wildlife populations, and appears to result in a significant increase in risk to some human populations. Because of its extensive use and environmental transport mechanisms, toxaphene use results in a significant risk of adverse ecological effects. It poses risks of chronic effects (e.g., backbone effects) to aquatic, avian and mammalian species, and in particular to fish. Exposure to the species of concern can result through direct application, aerial transport, or toxaphene runoff from treated fields or from cattle holding areas, and from leaching or overflow from toxaphene disposal sites. In addition, the risks of acute toxicity to aquatic organisms and population reductions in non-target organisms are posed to sensitive species which may be exposed to toxaphene by numerous exposure mechanisms, including those cited above. Because of contamination of their habitats and food sources, endangered fish and avian species are also subject to these chronic and acute effects.

Animal tests suggest that toxaphene could pose an oncogenic risk to humans. Of particular concern are local populations of fish consumers in areas where significant fish contamination has been demonstrated (e.g., Mississippi Delta and Great Lakes), and certain field applicators. This actions will mitigate such potential risk to humans.

Based on the information summarized above, the Agency has determined that toxaphene use poses a risk of significant adverse impacts on man and the environment. The total impact is expected to be greatest in toxaphene-use areas, but toxaphene-related risks may be felt far beyond those areas because of potential environmental transport.

B. Determination of Benefits

Toxaphene is registered for use as an insecticide and herbicide with a wide variety of use patterns on about 300 sites. Approximately 33 million pounds of toxaphene were applied to cropland and livestock in 1976; of that usage, 22 million pounds were applied to cotton. Since 1976, toxaphene annual usage on cotton has declined to an estimated 2.5 million pounds or less; total annual usage has declined to approximately 16 million pounds.

The Agency has determined that cancellation of registrations for most uses of toxaphene will not have a significant impact on production and prices of agricultural commodities or on the agricultural economy. The Agency has estimated that the benefits of toxaphene use are minimal due to the widespread introduction of the pyrethriods, sulprofos, and other competitively priced, more efficacious alternative pesticides, and the lowered efficacy of toxaphene due to the increased tolerance of insect pests to the chemical, except for sicklepod control on soybeans an peanuts, scabies treatment of beef cattle and sheep, and certain minor uses. Approximately $8.8–$19.7 million aggregate yield and quality losses are predicted to result if toxaphene becomes unavailable for sicklepod control (1981 dollars). Increased control costs and possible increased mortality of beef cattle also would result if toxaphene or a viable alternative were not available for scabies control. The minor uses include the use of toxaphene to control armyworms, cutworms and grasshoppers on cotton, corn and small grains in epidemic situations when alternative pesticides are either exhausted or ineffectual. Because of the crisis nature of the need for toxaphene in these instances, it is impossible to estimate the annual economic impact if toxaphene were not avaiable. However, when the need does arise, it is clear that there would be a significant impact on the agricultural economy if toxaphene were not available.

Other minor uses where continued use of toxaphene is considered critical and consequently of high benefit are mealybugs and pineapple gummosis moth control on pineapples and weevil control in bananas in the Virgin Islands and Puerto Rico.

III. Initiation of Regulatory Action

Based upon the determination summarized above and discussed in detail in Position Document 1 and the Toxaphene Decision Document, the Agency has determined that the risks arising from most uses of toxaphene are greater than the social, economic, and environmental benefits of those uses.

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Accordingly, the Agency has determined that immediate cancellation of toxaphene registrations for those uses is the only appropriate course of avoid unreasonable adverse effects upon the environment. Because of the unavailability of suitable efficacious alternatives, registrations products for scabies treatment of beef cattle and sheep are retained. Continued registration is contingent on significant modifications in the terms and conditions regarding use and regarding disposal of used solution. Because of problems associated with this use, the Agency will monitor the development of alternatives on an ongoing basis. Toxaphene products may continue to be registered for the control of armyworms, cutworms and grasshoppers on cotton, corn, and small grain, if changes are made in the terms and conditions of their registrations which, among other things, limit use to situations where a prior finding of emergency need for toxaphene has been made in these circumstances. Toxaphene products may continue to be registered for control of mealybugs and pineapple gummosis moths in pineapples and weevils in bananas so long as the registrations are for use ony in Puerto Rico and the Virgin Islands and are modified to include certain restrictive requirements. Existing stocks of toxaphene may be used for specified periods of time under very limited terms and conditions partly because such use is judged to be the most desirable means of achieving disposal of those stocks.

The specific details of the Agency's preliminary regulatory decision are set forth below:

A. All Uses

Except as provided below, all registrations for pesticide products containing toxaphene are cancelled, effective as of the end of the statutorily prescribed 30-day period.

B. Manufacturing Use Products

Registrations of products for use solely as manufacturing use products or technicals must be amended in accordance with the following requirement:

Labels must state that the product is for use only to formulate pesticide products which are registered in accordance with the Notice of Intent to Cancel or Restrict Registration of Pesticide Products Containing Toxaphene.

C. Scabies Control on Beef Cattle and Sheep

Toxaphene products may be registered for use to control scabies on beef cattle and sheep, subject to the terms and conditions noted below.

To avoid immediate cancellation, registrants who wish to retain the beef cattle and sheep dip use for their products must request that their registration be amended by revising the products' labels to provide that:

1. The product may be used only to treat scabies on beef cattle or sheep.

2. Application may be made only by dipping exposed or infected beef cattle or sheep in toxaphene vat solutions, or by using a spray-dip machine.

3. The products are classified as Restricted Use pesticides (for use only by certified applicators).

4. Label directions relating to vat cleaning and mixing are included to assure that the handling of materials and maintenance of percentage of toxaphene in the mix protect applicators. Prohibitions against disposal or dispersal to ponds, lakes, streams and other water bodies must also be included.

5. Applicators must wear boots, extended impermeable gloves, head covering, aprons, long pants, long-sleeved shirts, and respirators.

6. Used dip solutions must be disposed of in accordance with the Resource Conservation and Recovery Act (RCRA). If the owner generates more than 1000 kg of used dip solution per month or more than 1000 kg used dip solution in combination with other hazardous waste, the material must be treated as a hazardous waste subject to subpart C of RCRA. Any user who wishes to manage hazardous waste must obtain a permit to serve as a hazardous waste facility pursuant to RCRA. The label may exempt from these disposal requirements any farmer/rancher who uses the product solely to treat beef cattle or sheep which he and/or his immediate family owns as individuals.

7. Manufacturing and/or formulation of products for this registered use must be in accordance with III G. below.

D. Minor Uses: Armyworm/Cutworm/Grasshopper Control

Toxaphene products may be registered for use to control sporadic infestations of armyworms, cutworms or grasshoppers on cotton, corn, and small grain, subject to the terms and conditions noted below. To avoid immediate cancellation, registrants who wish to retain this use for their products must amend their registrations to provide for the following label requirements:

1. The amended labeling must be restricted solely to treatment of armyworms, cutworms, or grasshoppers on cotton, corn, or small grains.

2. All sale, offers for sale, holding for sale, distribution, shipment, delivery for shipment, receipt for shipment, offers for delivery, and use are restricted to emergency situations. Accordingly, all labels must provide that sale, distribution or use is permitted only after a showing of emergency conditions to EPA by a Federal or State agency and issuance by EPA of a finding that an emergency condition exists. The showing must be particularized regarding the extent of the infestation and proposed treatment (e.g., acreage involved, poundage of toxaphene needed, period during which treatment is permitted, application methods), and any finding that emergency conditions exist may impose restrictions relating to; among other things, geography, crop site, poundage, or duration. Agencies and States may of course anticipate conditions which would constitute an emergency and obtain approval in advance to use the product if the State or Federal agency shows that conditions prevail which are precursor to emergency conditions.

3. Toxaphene products registered for use to control armyworms, cutworms or grasshoppers on cotton, corn, and small grains must bear a Restricted Use classification (for use only by certified applicators.)

4. For Aerial applications, flagging must by fully automated mechanical means or by humans working in totally enclosed vehicles.

5. Protective clothing and respirators must be required for all applicators and other personnel involved in mixing, loading, transferring or otherwise handling this pesticide. Protective clothing must consist of hats, impermeable golves, rubber or synthetic rubber boots or boot covers, long-sleeved shirts and long pants. Full-face respirators are recommended; half-face respirators are required.

In lieu of compliance with the protective measures required for applicators, users may use closed system methods of mixing, loading and handling. However, it is recommended that mixers and loaders wear water proof gloves. Aerial applicators in positive pressure cockpits and other applicators in comparable ground equipment with appropriate filters at all air intakes need not comply with these protective clothing requirements.

6. Labers (Environmental Hazard section) must contain the following statement:

> This product is toxic to fish, birds and other wildlife. Use of this product may be

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fatal to birds and other wildlife in treated areas. Do not spray over lakes, streams, ponds, tidal marshes and estuaries. Do not apply where runoff is likely to occur. Do not apply when weather conditions favor drift from areas treated. Do not contaminate water by cleansing of equipment, or disposal of wastes. Overspray of this product into water at application rates recommended on this label may be fatal to shrimp and crab; do not apply where these are important resources. Apply this product only as specified on this label.

7. Manufacturing and/or formulation of products for this registered use must be in accordance with III G. below.

E. Minor Uses: Mealybug and Pineapple Gummosis Moth Control on Pineapples and Weevils in Bananas

Toxaphene products may be registered for use to control mealybugs and pineapple gummosis moth on pineapples and weevils in bananas, subject to terms and conditions noted below. To avoid immediate cancellation, registrants who wish to retain this use for their product must amend their registrations to provide for the following label requirements.

1. The use must be restricted solely to treatment of mealybugs and pineapple gummosis moths on pineapples and weevils in bananas.

2. The labeling must state "For Use Ony in Puerto Rico and the Virgin Islands."

3. The labeling must state that the product bears a Restricted Use classification (for use ony by certified applicators).

4. For aerial applications (if any), flagging must be by fully automated mechanical means or by humans workng in totally enclosed vehicles.

5. Protective clothing and respirators must be required for all applicators and other personnel involved in mixing, loading, transferring or otherwise handling this pesticide. Protective clothing must consist of hats, impermeable gloves, rubber or synthetic rubber boots or boot covers, long-sleeved shirts and long pants. Full-face respirators are recommended; half-face respirators are required.

6. Manufacturing and/or formulation of products for this registered use must be in accordance with III G. below.

F. Existing Stocks Provision

Pursuant to section 6 of FIFRA, the following provisions relate to existing stocks of cancelled toxaphene products existing within the territorial United States on or before the date of publication of this Notice in the Federal Register.

1. Existing stocks are defined as any toxaphene formulated for end use, any technical toxaphene, and any materials obtained and possessed by a registrant for use in manufacturing toxaphene which cannot be diverted for any other use by the registrant or for sale on the open market for any purposes other than manufacture of toxaphene.

2. Within thirty days from the date of receipt of this Notice, any registrant holding existing stocks of toxaphene, as defined in III F. 1 above, may provide the Agency with a request to qualify for the provisions for existing stocks provided by this Notice, and shall provide the Agency with an itemized inventory of its stocks. Failure to submit such a request will result in a requirement that any cancelled stocks possessed by a non-requesting registrant be disposed of within 90 days of publication of this Notice. Such disposal must be in the manner required by the Resource Conservation and Recovery Act. Each registrant who qualifies for the existing stock provision shall submit on each annual anniversary of this Notice, an update of the inventory, including depletion of the inventory, sufficiently detailed to allow the Agency to follow dispersal of the original inventory.

3. Existing stocks may be applied only on the sites described in III F. 4 a. below (in addition to the retained registered uses).

4. Except as provided in III F. 7 below, these stocks may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered for delivery to any person until the time periods specified in subparagraph 4.a. below, only when accompanied by supplemental labeling which contains the following limitations and conditions:

a. Stocks which consist of or can be made into formulations suitable to the uses designated in this paragraph must be labeled for use only to control sicklepod in soybeans and peanuts in those states which presently have 24(c) registrations or in an any other State which, during this period, makes a special local need finding; for use to control insects in corn cultivated without tillage and in dry and southern peas; for emergency use pursuant to III F. 5 below only until December 31, 1986. Stocks which consist of formulations which cannot be made suitable for the uses listed above, may be applied in accordance with the use patterns contained on present labeling for such stocks and may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received to be held for delivery by any person only until December 31, 1983.

b. For aerial applications, flagging must be by fully automated mechanical means or by humans working in totally enclosed vehicles.

c. Protective clothing and respirators must be required for all applicators and other personnel involved in mixing, loading, transferring or otherwise handling this pesticide. Protective clothing must consist of hats, impermeable gloves, rubber or synthetic rubber boots or boot covers, long-sleeved shirts and long pants. Full-face respirators are recommended; half-face respirators are required.

In lieu of compliance with the protective measures required for applicators, users may use closed system methods of mixing, loading and handling. However, it is recommended that mixers and loaders wear water proof gloves. Aerial applicators in positive pressure cockpits and other applicators in comparable ground equipment with appropriate filters at all air intakes need not comply with these protective clothing requirements.

d. Labels must contain the following statement: This product is toxic to fish, birds and other wildlife. Use of this product may be fatal to birds and other wildlife in treated areas. Do not spray over lakes, streams, ponds, tidal marshes and estuaries. Do not apply where runoff is likely to occur. Do not apply when weather conditions favor drift from areas treated. Do not contaminate water by cleansing of equipment, or disposal of wastes. Overspray of this product into water at application rates recommended on this label may be fatal to shrimp and crab; do not apply where these are important resources. Apply this product only as specified on this label.

5. Additional uses may be permitted of existing stocks until December 31, 1986, with appropriate supplemental labeling, upon a showing by any Federal or State agency that emergency conditions exist and a finding by EPA that the emergency conditions warrant use of these existing stocks for the requested purpose.

6. The supplemental labeling required by III F. 4 above may accompany present labeling of the product appropriately identified as a cancelled product permitted for distribution, sale, offers for sale, holding for sale, shipment, delivery for shipment, receipt to delivery or use only until December 31, 1986. Alternatively, registrants may modify present labeling to incorporate the supplemental labeling so long as the modified labeling is accepted by the Agency to contain all necessary provisions from the labels of the cancelled products and properly identifies the product as permitted for

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sale, distribution, and use only until December 31, 1986.

7. Existing stocks not within the physical possession of any registrant (e.g., possessed by dealers and retailers) may be sold, shipped, or distributed for use in accordance with the labeling presently accompanying the product until December 31, 1983. Stocks within the physical possession of a registrant include, but are not limited to, stocks stored in facilities owned or leased by the registrant. Existing stocks in the hands of users on or before December 31, 1983 may be used in accordance with the labeling accompanying the product in the hands of the users.

8. Pursuant to the authority of FIFRA section 6(a)(1), existing stocks of any toxaphene product whose registration is cancelled pursuant to this Notice may not be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, received for delivery, or offered for delivery by or to any person or used by any person in any State in any manner which would violate FIFRA section 12 if the product were still registered. Except as provided in III F. 7 above, such products shall be made available for use only by, and used only by, certified applicators or persons under the direct supervision of a certified applicator, and the supplemental labeling shall so state. For purposes of this paragraph, and FIFRA sections 12(a)(1) (B) and (C), the term "statement required in connection with [the product's] registration" shall mean the statement on file with the Administrator in connection with the product's registration on the effective date of cancellation of the product, as modified by labeling changes required by this Notice, or by other modifications approved by the Administrator.

9. After December 1, 1986, existing stocks may not be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, received to deliver, or used for pesticidal purposes, and any stocks of products which are unused after that date must be disposed of in the manner prescribed by the label or as required by the Resource Conservation and Recovery Act.

G. Limitation on Toxaphene Sources

The Agency has determined that the provision to permit use of existing stocks should be designed in a manner that provides for the minimum total loading of toxaphene into the environment which is sufficient to permit use of the stocks. Accordingly, beginning thirty days from receipt of this Notice by the registrant, all formulations of toxaphene for registered uses must be made from material designated as existing stocks under the terms and conditions of this Notice. This requirement shall be in effect until (1) December 31, 1986 or (2) such time as the Agency finds that any registrant has made a showing that existing stocks are no longer available from which to formulate products for the registered uses, whichever is earlier.

IV. Comments of Scientific Advisory Panel and Secretary of Agriculture

A. Comments of Former Members of the Scientific Advisory Panel

Pursuant to section 25(d) of FIFRA, notices of intent to cancel issued under section 6(b) are to be submitted to an advisory panel "for comment as to the impact [of the proposed action] on health and the environment." At the time the Agency completed its review of toxaphene, the statutory authorization for the Scientific Advisory Panel (SAP) and expired; to date, a new panel has not been authorized and referral is therefore not required by law. However, in order to obtain peer review of its scientific evaluations and conclusions, the Agency submitted draft risk estimates, copies of the NCI and Litton-Bionetics bioassays, the Agricultural Runoff Model information, and a draft exposure/risk assessment to the former members of the SAP for review and comment. The Agency specifically requested the scientists to comment on several important scientific issues in the areas of human risk assessment. The Agency received comments from the six former SAP members which are excerpted and/or summarized below. These comments do not require direct response by the Agency, as they are consistent with the regulatory actions set forth in this Notice.

1. *Human risk assessment—a. General.* There was no real problem with the risk estimate calculations although the risk estimate should have been calculated on the thyroid effect rather than on the male mouse hepatoma effect. While this would decrease the risk slightly it would link the calculation to an effect that is less controversial than the predictive value of the B6C3F1 mouse liver.

The Agency used the log probit and one hit model for quantifying the oncogenicity risk of hepatocellular cancer. These two models are the models which have been used by the Agency in the past. They have been recently questioned by some statisticians. The linear multistage model is the model currently in favor and it appears that this model actually gives risk estimates which are even higher than those obtained by the use of the more traditional estimates.

The epidemiologic data and the analysis of toxaphene in the air, runoff water, and in food supply (fish bioaccumulation) indicate that toxaphene presents a special hazard for the general population. The magnitude of this hazard is difficult to quantify but there can be little argument with the possibility that toxaphene is a carcinogen that can accumulate in our food chain, a fact regarded as more significant than the actual numbers generated by the Weibull or other types of analysis.

The strong evidence of the biomagnification of toxaphene and its entry into the human diet, especially through fish in the S.E. United States, where levels may exceed the Acceptable Daily Intake (ADI), has clearly demonstrated the presence of a high risk associated with the present use of toxaphene.

b. *Human exposure.* The exposure data for humans suggest that workers, applicators, and farmers seem not to be at risk when utilizing toxaphene, at least with the methods available for detection they do not seem to get the pesticide internalized. This all augers well until the point is made that an individual who served as a control had significant adipose tissue levels of toxaphene. The search for the source of his levels reveals that he ate fish, and that the meat of the fish itself was a source. The necessary assumption that comes from this observation is that regardless of what may happen with toxaphene in the environment suggested by the models of the Yazoo Basin, the fact is that bioaccumulation does occur. The fact that one individual attained significant body levels simply by eating fish is the telling point. This necessarily implies an environmental contamination.

(1) *Dietry exposure.* Extensive and well documented studies of toxaphene levels in the U.S. diet demonstrate that the average daily intake of this pesticide, especially in S.E. United States, substantially exceeds the ADI.

The data of toxaphene levels in drinking water, or rather the lack of it, necessitated exclusion of estimates from this source of exposure, but fish ingestion is clearly of importance, especially in the southeastern United States. In a similar situation in Triana, Alabama, the DDT exposure sustained by the local population through the eating of fish contaminated by DDT contributed to a high body burden of this pecticide, emphasized the need to measure this special dietary exposure in the southeastern U.S. where toxaphene

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contamination of fish appears to be increasing. The paper entitled "Organochlorine Pesticide Residues in Fish". (National Pesticide Monitoring Reports 1970–74) supports that 50 percent contamination of fish with toxaphene is in the southeastern United States.

(2) *Occupational exposure.* Because estimates of worker exposure to toxaphene also suffered from a lack of available residue data a lot of assumptions had to be made, some of which seemed reasonable, others which were rather speculative. There is no difficulty with the inhalation estimates nor is there a question of the fact that 15 percent of applicator's skin would be unprotected. What is not known is the actual dermal absorption of toxaphene through human skin and application rates may in actual fact be increasing because of the resistance problem. No other way could be seen that the estimates of occupational exposure could have been made and the steps that the Agency has taken to attempt to quantitate worker exposure are concurred with.

c. *Carcinogenicity.* It is clear from results of the NCI bioassay and the Litton Bionetics study that toxaphene causes hepatocellur carcinomas in male and female B6C3F1 mice as do most of the chlorinated hydrocarbon pesticides. However, toxaphene also caused follicular cell carcinomas and adenomas in the Osborne Mendel rats used for thee studies. Although the studies with other species (dogs, monkeys, and hamsters) are reassuring in regard to the carcinogenic effect, the most important finding in the chronic studies on toxaphene in the thyroid effect.

d. *The need for epidemiologic studies—potential epidemiologic approaches.* The risk conclusions reached for heptaic cancer are very high. If toxaphene presents risks of these orders of magnitude, then these should not be beginning to appear. Toxaphene is very like DDT in may ways. It is highly persistent, has been around since 1947 and hepatomas are the tumors seen in animals. The main difference is in the fact that exposure to a compound cannot be readily measured, though apparently John Cassida recently described an improved method for measuring 6 of the camphenes.

In their review of the causes of cancer in the U.S.A., Doll and Peto comment "It is notable, however, that there has been no general increase in the incidence of liver tumors since the long lasting pesticides were introduced, despite the fact that hepatomas are the principal type of cancer to have been reported in laboratory animals under experimental conditions. During 1968–1978, at ages under 65, there was a non-significant decrease in male mortality and a non-significant increase in female mortality due to heptacellular carcinoma although liver cancer remains virtually incurable." Reassuring as is this finding, it should be remembered that a breakdown of the data for geographical regions was not analyzed, and neither was there a race specific evaluation of the data. The latter may be important because for DDT, residues in blacks in two national surveys have increased with age, an increase which was noted beyond the DDT age of the study sample in each of the surveys. Thus, there might be a partial genetic problem in the elimination of some of the persistent pesticides.

With regard to place differences and the special exposures of the Southeast to toxaphene, since this has been around for 20 years, if the risks postulated are valid, we should see hot spots for liver cancers in these areas. The Mason and McKay maps (which only go up to 1970) have been looked at and it has been noted that there are two counties in Louisiana which have age adjusted rates for cancer mortality due to biliary passages and liver which are significantly high and in the highest decile. The same is true for black males but its not seen for white or black females.

2. *Environmental risk assessment—a. General.* This section of the document was found to be complete (to the extent possible) and the data properly, but conservatively, interpreted. The risks were adequately presented except for the puzzling omission of data on reproduction. The evaluation of risk is conservative. If more data were available it is possible they would show additional and greater risk.

b. *Agricultural runoff model.* The model is a challenging mixture of facts, assumptions, and speculation which is the best one can do in our state of ignorance. The model makes sense and is a necessary approximation to reality. There are no reservations in drawing conclusions from it.

c. *Persistence, bioaccumulation, and transport.* Toxaphene is persistent, bioaccumulates, and moves easily through soil and water, thus presenting severe hazards that are difficult to mitigate. Due to toxaphene's persistence and transport, runoff is a special hazard since toxaphene accumulates in aquatic systems where it bioaccumulates and readily exceeds LD_{50} levels.

d. *Toxicity to fish.* The toxicity to fish is abundantly documented by good dose-response curves. Toxaphene damages fish (broken back syndrome) and thus has a unique and special ecological effect.

Toxaphene is extremely hazardous to fish both in wildlife and in fish culture and its use has resulted in massive fish kills as well as a crippling collagen deformity of unknown etiology that is produced at very low levels (ca 50 ppt) and can seriously affect fish development and reproduction. EPA's massive study of "Toxaphene Migration and Risk in the Yazoo River Basin, Mississippi," supports through substantial scientific methodology the conclusions already drawn through more than 30 years of intensive use, i.e. that exposure to dissolved toxaphene in a river (and lake) ecosystem can cause short and long term damage to game fish populations. In short, toxaphene, because of its extremely high toxicity to fish and its massive use as a cotton insecticide, poses a much more severe threat to game fish populations than any other insecticide, including endrin which was prohibited for use in Eastern United States by EPA in 1980 because of its hazard to fish and other aquatic life.

e. *Toxicity to birds and mammals.* The toxicity to birds and mammals is not high but the process of bioaccumulation results in excess dosages. Hence, bird kills occur frequently.

It is clear from the brief description given in the carcinogenicity assay that both acute and chronic toxicity are demonstrable in rodent species. Unfortunately these are neither extensively described nor clearly defined; but rough fur, weight loss, and bloating all suggest that toxaphene has systemic toxicity and the neurotoxicity that goes along with it is mentioned in passing. Whether or not it is a carcinogen is important, but if it has both acute and chronic toxicity to this degree of magnitude, then one must define what these toxicities are in order to anticipate what changes do occur in the environment. The fish disease that has been described is a case in point. Taken altogether, the data that is available suggest that toxaphene does pose a significant biological hazard, that our fund of information concerning the nature of this hazard is quite limited, and that we are really troubled by an absence of solid residue data.

f. *Endangered species.* The use of toxaphene in the Southeast United States where eagles feed on fish presents a hazard to this endangered species.

3. *Continued toxaphene use.* In view of the great mass of evidence available, toxpahene must be viewed as a real and

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unacceptable hazard to both humans and the environment. It would appear that this hazard can only be eliminated be either removing toxaphene from the market place or by restricting its use in such a manner that the hazard is reduced to acceptable levels. Toxaphene is outmoded and at best deserves only a limited place in the contemporary pesticide arsenal.

B. Comments of the United States Department of Agriculture

Throughout the RPAR review of toxaphene, the Aency periodically consulted with the U.S. Department of Agriculture (USDA) on matters relating to toxaphene uses, including the expected impact of cancellation of toxaphene on the agricultural economy. Section 6(b) of FIFRA specifically requires that all 6(b) notices be sent, with an analysis of the impact of the proposed action on the agricultural economy, to the Secretary of Agriculture for comments, and that any comments received from the Secretary and the Administrator's response to those comments be published with the final notice of determination.

1. *USDA comments.* The comments of the Department of Agriculture regarding the Preliminary Notice of Determination Concluding the Rebuttable Presumption Against Registration of Toxaphene are presented below in their entirety.

September 24, 1982.

Mr. Edwin L. Johnson (TS–768C),
Director, Office of Pesticide Programs, U.S. Environmental Protection Agency, Washington, D.C.

Dear Mr. Johnson: This is the United States Department of Agriculture's (USDA) response to the U.S. Environmental Protection Agency's (EPA) Preliminary Notice of Determination concluding the Rebuttable Presumption Against Registration (RPAR) of pesticide products containing toxaphene. Specific discussion of various uses is contained in the attachment to this letter.

State research and extension personnel responsible for pest control technology and recommendations were contacted by UDSA concerning the agricultural needs for toxaphene. These experts expressed the view that many of the currently registered uses of toxaphene remain important to certain segments of U.S. agricultural production and the registration of these uses should be continued. USDA concurs with these needs and believes that no action should be taken on these uses until new, effective and economical control measures are developed and registered for use. At this time, the marketplace will appropriately reduce and replace the need for toxaphene. However, if deemed appropriate or necessary, cancellation actions could be considered when new effective and economical alternatives to toxaphene are available. This approach would not only resolve the health and environmental concerns about toxaphene, but also would not place an excessive burden on American agriculture by cancelling currently needed toxaphene registrations before acceptable replacement control measures are available.

As outlined in the attachment to this letter, toxaphene provides effective and economical insect control for a number of minor use problems that would not otherwise be attainable. Further, allowing continued registration of these uses will not result in any more toxaphene actually being applied than would be applied under the EPA proposed regulatory scheme and this procedure would be far less costly and demanding to administer.

We do not concur that phaseout approaches represent an effective means of resolving potential health and environmental problems. We encourage EPA to consider other regulatory procedures, such as restricted use and appropriate label restrictions, to accomplish the desired level of regulatory control of toxaphene, if such is necessary to prevent adverse health and/or environmental effects. As is pointed out, and for the reasons stated in the attachment, we do not support the use of Section 18 emergency exemptions as a regulatory mechanism in this situation.

We recommend that EPA give favorable consideration to the needs expressed by States as outlined in the attachment to this letter and those stated in our letter of July 28, 1982. Those specialty crop and site situations have special economic significance due to specific pest problems, local situations, and for individual producers.

Sincerely,

T. B. Kinney, Jr.,
Acting Assistant Secretary, Science and Education.

Enclosure

Attachment to the Department of Agriculture's Response to the Environmental Protection Agency's Position Document on Toxaphene

The Department, as expressed in our letter of July 28, remains concerned that there are still several specialty crop and site situations in addition to those recognized by EPA, for which there is still a significant need for toxaphene under certain conditions. Recent information obtained from the States strongly indicates that toxaphene is still the preferred treatment for a variety of situations, including:

1. Ectoparasite control on livestock with special emphasis on quarantine and regulatory programs;
2. control of certain insects on corn, small grains, sunflowers, soybeans, alfalfa for seed production, range, pasture, garlic seed crops, peppers, dry peas, southern peas, and onions;
3. mealybug control on pineapple roots and weevils in bananas in the Virgin Islands;
4. sicklepod control in soybeans;
5. control of sporadic early season cutworm infestations in southern cotton.

Variable pest populations, environmental and ecological conditions and economic factors will dictate the need for selective use of toxaphene, especially in these specialty crop situations where control alternatives are either nonexistent or comparatively ineffective. For example, in small grains, soil insects and grasshoppers can thrive in cold, damp weather, causing populations to build up rapidly in the early spring and late fall. Toxaphene is the only effective control for these pests under those environmental conditions. In addition soil insect populations are significantly higher in croplands under minimum tillage practices. Toxaphene is the most efficacious material for the control of insect populations located in the soil.

It is our view that regulating toxaphene as a restricted use pesticide, coupled with appropriate label restrictions, rather than allowing use only under emergency conditions, will provide more than adequate regulation. In this situation, a system which allows use only under emergency conditions, as proposed by EPA in the decision document, would be very cumbersome and costly to administer. Labeling containing specific use criteria could be developed which would accomplish the same intent.

The use of the FIFRA Section 18 mechanism is predicated on the fact that a material which is selected for use is not registered for that use. This seems to make the use of this mechanism, in this case, inappropriate. Also, it is our belief that maintaining those uses identified above and regulating those uses primarily through the restricted use mechanism and the label, will result in no more toxaphene actually being applied than envisioned by EPA under its proposed regulatory strategy. We are, as suggested in your August 27 letter, available for further discussion of these issues.

Regarding the use of toxaphene for scabies control, the decision document proposes restriction to vat use only. Spray-dip machines have been used and are desirable for the small lot or herd because of their portability. Further, where they can be used, they are environmentally more acceptable since far less solution remains when the job has been completed. (We are attaching a copy *Veterinary Services Memorandum 556.5, Guidelines for Use of Spray-Dip Machine for Treating Cattle.*)

A number of scientists in USDA have reviewed EPA's decision document and had difficulty reconciling the divergent viewpoints and concerns expressed in the document. For example, on page III–16, the document discusses sources of chlorinated terpenes. Because of uncertainties in the analytical method, any source of toxaphene other than direct application, drift or runoff from a recently treated site must be considered hypothetical, which is why analyzed toxaphene residues are often termed "toxaphene like" residues. A more thorough discussion of possible sources of "toxaphene like" residues, including a discussion or the importance of this confounding information to the regulatory decision would significantly clarify this section of the document.

On the 18th unnumbered page of the proposed notice at item 8, it appears that the agency is attempting to make nonregistrants, including those who make "use of existing stocks pursuant to" the EPA provisions, subject to the same FIFRA requirements as

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registrants. We do not concur with EPA's treatment of sellers and users as registrants. They will be sufficiently regulated when toxaphene becomes a restricted use pesticide. We feel that this provision, as worded, will place unwarranted liability on farmer users and also USDA employees who apply the material.

On the same page at item 9, we feel that the Agency should clarify the basis for its proposal to bar imports of a registered pesticide. This action could favor one registrant over another and also could significantly increase costs to users.

Finally, in relation to phaseout programs, the synthesis and screening of new compounds and the development of biological controls is a continuous, ongoing activity of the research community, but the end products and timeframes for accomplishing them are not predictable.

2. *EPA response.* The Agency disagrees with USDA's general position that no cancellations of toxaphene are necessary to resolve the health and environmental concerns about toxaphene. Contrary to USDA's assertion that "allowing continued registration of [a number of] uses will not result in any more toxaphene actually being applied than would be applied under the EPA proposed regulatory scheme", the cancellation of most toxaphene uses and limitation of use of existing stocks to certain crops and to a specified time period will greatly reduce the total burden of toxaphene residues in the environment.

USDA's statement that regulatory restrictions such as improved labeling and restricted use classification should be chosen instead of cancellation "if [regulatory control] is necessary to prevent adverse health and/or environmental effects" ignores the characteristics of toxaphene which result in persistent environmental contamination, regardless of application and use practices. Moreover, EPA cannot accept USDA's apparent premise that a determination whether to cancel a pesticide's registrations should be based on whether and when "new, effective, and economical control measures are developed and registered for use." The availability of alternatives is only one element of the evaluation necessary to determine whether a pesticide's uses cause unreasonable adverse environmental effects. In any event, EPA has found that efficacious and econonmic alternatives are available for the toxaphene uses indentified by USDA except to the extent reflected in the final regulatory decision on toxaphene.

However, a number of USDA's comments are well taken and have been incorporated into the Agency's final Notice. These comments and EPA's response are as follows:

a. Recommendations for continued registration to control scabies on livestock other than cattle and for use of spray-dip machine to treat livestock.

EPA has continued registration to control scabies on beef cattle and has added sheep to the permissable sites. The spray-dip machine treatment method has been added as a permissable application method.

b. Recommendation for continued registration to control mealybugs on pineapple roots and weevils in bananas in the Virgin Islands.

EPA has confirmed the value to the agricultural economy of the Virgin Islands from continuation of this use and has determined that the rationale applies to Puerto Rico as well and to control of the pineapple gummosis moth in these areas. Accordingly, continued registration for these very low volume uses is permitted.

c. Recommendation to retain other registered uses which, in its view, are important to certain segments of the agricultural economy.

EPA has carefully assessed these uses and finds that cost-effective, efficacious alternatives are available, except in some instances, for dry and southern peas. Accordingly, the Agency is allowing the use of existing stocks for these uses.

d. Recommendation to clarify language applying FIFRA provisions to persons qualifying for the existing stocks provision.

This language has been altered so that existing stocks are treated like registered pesticides for purposes of enforcing FIFRA provisions.

e. Recommendation to clarify "import" provision. The Agency has clarified reference to limits on imports contained in the draft Notice. The only "imports" provision which the Agency seeks to impose is a limitation on import and production of toxaphene such that, to the extent feasible, existing stocks will be used for all registered products until such stocks are exhausted.

USDA's remaining comments do not provide any documented basis for alteration of the agency's Notice or regulatory decision. For example, the Agency has considered the matters raised by USDA relating to whether the apparent toxaphene residues found distant from use sites are in fact toxaphene, or if the residues can be explained by althernative hypotheses. The Agency has received no information from USDA or elsewhere which adequately demonstrates the validity of any alternative hypothesis, and efforts to discover credible alternative explanations have not resulted in any basis for rejecting the conclusions that these measured residues are, in fact, toxaphene. The uncertainties and difficulties posed in analyses of these residues are discussed in the Toxaphene Decision Document.

USDA also criticizes the requirement of a showing of emergency circumstances prior to application of toxaphene for the registered uses to control certain sporadic insect infestations on small grains, corn, and cotton. USDA states that the "Section 18 [of FIFRA] mechanism is predicated on the fact that a material which is selected for use is not registered for that use." The labeling requirement for a prior showing of emergency circumstances, however, is not made pursuant to section 18 of FIFRA and serves different purposes. In particular, it assures that any significant contribution of additional toxaphene to the total environmental load will be permitted only in light of significant benefits from the use and only to the limited extent determined appropriate in light of the emergency circumstances.

V. Procedural Matters

This Notice announces the Administrator's intent to cancel registrations of products containing toxaphene for most uses, and to restrict registrations for the remaining uses to use by certified applicators. This Notice also announces the administrator's decision to deny any applications for registrations of pesticide products containing toxaphene unless they comply with the requirements of this Notice. As provided in FIFRA section 6(b), the cancellations and denials proposed in this Notice "shall become final and effective at the end of 30 days from receipt by the registrant, or publication, of [this] notice, whichever comes later, unless within that time either (i) the registrant makes the necessary corrections, if possible, or (ii) a request for a hearing is made by a person adversely affected by the notice." Unless the necessary steps to make these changes are taken within 30 days, or unless a hearing is properly requested to contest the cancellation or denial of the registrations for specific toxaphene products, the cancellation or denial actions will become final at the end of 30 days. The 30-day time period in which to request a hearing is applicable to all the regulatory actions proposed in this Notice, includng the immediately effective cancellations; the registration restrictions on toxaphene products for control of scabies on beef cattle and sheep; the registration restrictions on toxaphene products for control of armyworms, cutworms, and

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grasshoppers on cotton, corn, and small grains; the registration restrictions on toxaphene products for control of mealybugs and pineapple gummosis moths on pineapples and weevils in bananas; the existing stocks provisions; and the denial of applications. This section of the Notice explains how registrants and applicants may seek to modify the terms and conditions of registration or applications to make any necessary corrections and how registrants, applicants, and other adversely affected parties may request a hearing on the cancellation actions set forth in this Notice.

A. Procedures for Amending the Terms and Conditions of Registration

To make the changes required to avoid cancellation, registrants and applicants within a 30-day period from receipt of this Notice must submit application(s) for new or amended registration(s) as appropriate, making the necessary corrections. The application for new or amended registration(s) must be submitted to: Jay Ellenberger, Product Manager, Registration Division (TS-767), Office of Pesticide Programs, Rm. 202, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703-557-2386).

B. Procedure for Requesting a Hearing

Registrants or applicants adversely affected by the cancellation or denial actions described above may request a hearing on such actions within 30 days of receipt of this Notice, or within 30 days from publication of this Notice in the Federal Register, whichever occurs later. Any other person adversely affected by the cancellation or denial actions described above may request a hearing within 30 days of publication of this Notice in the Federal Register.

All registrants, applicants, and other affected parties, who request a hearing must file the request in accordance with the procedures established by FIFRA and the Agency's Rules of Practice Governing Hearings (40 CFR Part 164). These procedures require among other things that (1) all requests must identify the specific registration(s) or application(s) by registration number(s) or file symbol and the specific use(s) for which a hearing is requested, (2) all requests must be accompanied by objections that are specific for each use of the identified pesticide products for which a hearing is requested, and (3) all requests must be received by the Hearing Clerk within the applicable 30-day period. Failure to comply with these requirements will result in denial of the request for a hearing.

Requests for a hearing must be submitted to: Hearing Clerk (A-110), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460.

C. Consequence of Filing or Failing To File a Hearing Request

1. *Consequence of filing a timely and effective hearing request.* If a hearing on any action initiated by this Notice is requested in a timely and effective manner, the hearing will be governed by the Agency's rules of practice for hearings under FIFRA section 6 (40 CFR Part 164). The hearing will be limited to the uses and registrations (or applications) as to which a hearing is requested.

2. *Consequences of failure to file in a timely and effective manner.* If no hearing is requested regarding specific registration(s) and/or specific use(s), the cancellation of such registrations or uses becomes effective thirty days after publication of this Notice or receipt by the affected registrants, whichever comes later. If a registrant wishes to contest the cancellation or required conditions for particular identified uses, but desires to modify the terms and conditions of his registration to secure continued registration of one or more of those uses permitted by this Notice, the registrant must apply for an appropriate new or amended registration as well as submit the hearing request.

Dated: November 10, 1982.

John A. Todhunter,

Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 82-32577 Filed 11-26-82; 8:45 am]

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